UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 O**
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2021

or

☐ **TRANSITION REPORT PURSUANT TO SECTION**
SECURITIES EXCHANGE ACT OF 1934

Commission file number 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**95-3540776**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive **Thousand Oaks** **California**	**91320-1799**
(Address of principal executive offices)	(Zip Code)

(805) 447-1000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol (s)	Name of each exchange on which registered
Common stock, $0.0001 par value	**AMGN**	**The Nasdaq Stock Market LLC**
2.00% Senior Notes due 2026	**AMGN26**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller re company
☒	☐	☐	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $137,531,019,585 as of June 30, 2021.[(A)]

(A) Excludes 811,415 shares of common stock held by directors and executive officers, and any stockholders whose ownership exceeds ten percent of the shares outstanding, at June 30, 2021. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

557,029,370

(Number of shares of common stock outstanding as of February 11, 2022)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2022 Annual Meeting of Stockholders to be held May 17, 2022, are incorporated by reference into Part III of this annual report.

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Defined Terms and Products

Defined terms

We use several terms in this Form 10-K—including but not limited to those that are finance, regulation and disease-state related—as well as names of other companies, which are given below.

Term	Description
2017 Tax Act	Tax Cuts and Jobs Act of 2017
AbbVie	AbbVie Inc.
ACA	Affordable Care Act
aHUS	atypical hemolytic uremic syndrome
ALL	acute lymphoblastic leukemia
AMD	age-related macular degeneration
Amended 2009 Plan	Amended and Restated 2009 Equity Incentive Plan
ANDA	Abbreviated New Drug Application
AOCI	accumulated other comprehensive income (loss)
AstraZeneca	AstraZeneca plc
BAFF	B-cell activating factor
BeiGene	BeiGene, Ltd.
BiTE®	bispecific T-cell engager
BLA	Biologics License Application
BMS	Bristol Myers Squibb Company
BPCIA	Biologics Price Competition and Innovation Act of 2009
Celgene	Celgene Corporation
CGRP	calcitonin gene-related peptide
chemotherapy	anticancer medicines
CHMP	Committee for Medicinal Products for Human Use
CIT	chemotherapy-induced thrombocytopenia
CKD	chronic kidney disease
CMS	Centers for Medicare & Medicaid Services
COSO	Committee of Sponsoring Organizations of the Treadway Commission
COVID-19	coronavirus disease 2019
CV	cardiovascular
DaVita	DaVita Inc.
DLL3	delta-like ligand 3
DOJ	U.S. Department of Justice
DoR	duration of response
EC	European Commission
EMA	European Medicines Agency
EPS	earnings per share
ERG	employee resource group
ESA	erythropoiesis-stimulating agent
ESG	environmental, social and governance
ESRD	end-stage renal disease
EU	European Union
FASB	Financial Accounting Standards Board
FCPA	U.S. Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FGFR2b	fibroblast growth factor receptor 2b
Fitch	Fitch Ratings, Inc.

Term	Description
Five Prime	Five Prime Therapeutics, Inc.
FOMBPR	Financial Oversight and Management Board for Puerto Rico
FTC	Federal Trade Commission
GAAP	U.S. generally accepted accounting principles
GDPR	General Data Protection Regulation
GEJ	gastroesophageal junction
HeFH	heterozygous familial hypercholesterolemia
HER2	human epidermal growth factor receptor 2
HGRAC	Human Genetic Resources Administration of China
HHS	U.S. Department of Health & Human Services
HLE	half-life extended
HoFH	homozygous familial hypercholesterolemia
ICOSL	inducible costimulatory ligand
IL	interleukin
IND	Investigational New Drug Application
IPR&D	in-process research and development
IRP	international reference pricing
IRS	Internal Revenue Service
ITP	immune thrombocytopenia
J&J	Johnson & Johnson
Janssen	Janssen Biotech, Inc.
K-A	Kirin-Amgen, Inc.
Kirin	Kirin Holdings Company, Limited
KKC	Kyowa Kirin Co., Ltd.
LDL-C	low-density lipoprotein cholesterol
LIBOR	London Interbank Offered Rate
Lilly	Eli Lilly and Company
mCRPC	metastatic castrate-resistant prostate cancer
MD&A	management's discussion and analysis
MFN	most favored nation
Moody's	Moody's Investors Service, Inc.
MRD	minimal residual disease
Neumora	Neumora Therapeutics, Inc.
NOL	net operating loss
Novartis	Novartis Pharma AG
NSCLC	non-small cell lung cancer
Nuevolution	Nuevolution AB
OECD	Organization for Economic Co-operation and Development
OIG	Office of Inspector General
ORR	objective response rate
PBM	pharmacy benefit manager
PCSK9	proprotein convertase subtilisin/kexin type 9
PDE4	phosphodiesterase 4
PDUFA	Prescription Drug User Fee Act
PFS	progression-free survival
PNH	paroxysmal nocturnal hemoglobinuria
Profit Sharing Plan	Amgen Profit Sharing Plan for Employees in Ireland
PROMESA	Puerto Rico Oversight, Management, and Economic Stability Act

Term	Description
PTAB	Patent Trial and Appeal Board
R&D	research and development
RANKL	receptor activator of nuclear factor kappa-B ligand
RAR	Revenue Agent Report
REMS	risk evaluation and mitigation strategy
ROU	right-of-use
ROW	rest of world
RSUs	restricted stock units
S&P	Standard & Poor's Financial Services LLC
SEC	U.S. Securities and Exchange Commission
SG&A	selling, general and administrative
siRNA	small interfering RNA
sNDA	supplemental New Drug Application
SoC	standard of care
SOFR	Secured Overnight Financing Rate
SRE	skeletal-related event
Takeda	Takeda Pharmaceutical Company Limited
TDAPA	transitional drug add-on payment adjustment
Teneobio	Teneobio, Inc.
TNF	tumor necrosis factor
TPO-RA	thrombopoietin receptor agonist
U.S. Treasury	U.S. Department of Treasury
UCLA	University of California, Los Angeles
USPTO	U.S. Patent and Trademark Office
UTB	unrecognized tax benefit
VEGFR	vascular endothelial growth factor receptor

Products

The brand names of our products, our delivery devices and certain of our product candidates and their associated generic names are given below.

Term	Description
Acapatamab	Acapatamab (formerly AMG 160)
Aimovig	Aimovig® (erenumab-aooe)
AMGEVITA	AMGEVITA™ (adalimumab)
AMJEVITA	AMJEVITA™ (adalimumab-atto)
Aranesp	Aranesp® (darbepoetin alfa)
AutoTouch	AutoTouch®
AVSOLA	AVSOLA® (infliximab-axxq)
BLINCYTO	BLINCYTO® (blinatumomab)
Efavaleukin alfa	Efavaleukin alfa (formerly AMG 592)
ENBREL	Enbrel® (etanercept)
ENBREL Mini	ENBREL Mini®
EPOGEN	EPOGEN® (epoetin alfa)
EVENITY	EVENITY® (romosozumab-aqqg)
IMLYGIC	IMLYGIC® (talimogene laherparepvec)
KANJINTI	KANJINTI® (trastuzumab-anns)
KYPROLIS	KYPROLIS® (carfilzomib)
LUMAKRAS/ LUMYKRAS	LUMAKRAS® / LUMYKRAS™ (sotorasib)
MVASI	MVASI® (bevacizumab-awwb)
Neulasta	Neulasta® (pegfilgrastim)
NEUPOGEN	NEUPOGEN® (filgrastim)
Nplate	Nplate® (romiplostim)
Olpasiran	Olpasiran (formerly AMG 890)
Onpro	Onpro®
Ordesekimab	Ordesekimab (formerly AMG 714)
Otezla	Otezla® (apremilast)
Parsabiv	Parsabiv® (etelcalcetide)
Pavurutamab	Pavurutamab (formerly AMG 701)
Prolia	Prolia® (denosumab)
Repatha	Repatha® (evolocumab)
RIABNI	RIABNI™ (rituximab-arrx)
Rozibafusp alfa	Rozibafusp alfa (formerly AMG 570)
Sensipar/Mimpara	Sensipar®/Mimpara™ (cinacalcet)
SureClick	SureClick®
Tarlatamab	Tarlatamab (formerly AMG 757)
TEZSPIRE	TEZSPIRE™ (tezepelumab-ekko)
Vectibix	Vectibix® (panitumumab)
XGEVA	XGEVA® (denosumab)

Products referenced in this report that are not included in the above list are trademarks of their respective owners. They are Avastin®, Cosentyx®, DARZALEX®, DARZALEX FASPRO®, EYLEA®, Fulphila®, Herceptin®, HUMIRA®, POMALYST®/IMNOVID®, PRALUENT®, PROCRIT®, PROMACTA®/REVOLADE™, Remicade®, REVLIMID®, RINVOQ®, Rituxan®/MabThera®, Skyrizi®, SOLIRIS®, STELARA®, Taltz®, Tremfya®, UDENYCA®, VELCADE® and Xeljanz®.

PART I

Item 1. BUSINESS

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is a biotechnology company committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen was incorporated in California in 1980 and became a Delaware corporation in 1987. We have a presence in approximately 100 countries worldwide. Amgen operates in one business segment: human therapeutics.

Significant Developments

Following is a summary of significant developments affecting our business that have occurred and that we have reported since the filing of our Annual Report on Form 10-K for the year ended December 31, 2020.

Business Development

Five Prime Therapeutics acquisition

- On April 16, 2021, Amgen completed its acquisition of Five Prime, a public clinical-stage biotechnology company focused on developing immuno-oncology and targeted cancer therapies, for approximately $1.6 billion in cash, net of cash acquired.
- In April 2021, the FDA granted Breakthrough Therapy designation for bemarituzumab as first-line treatment for patients with FGFR2b overexpressing and HER2-negative metastatic and locally advanced gastric and gastroesophageal adenocarcinoma in combination with fluoropyrimidine, leucovorin and oxaliplatin based on an FDA-approved companion diagnostic assay showing at least 10% of tumor cells overexpressing FGFR2b.

KKC collaboration

- We and KKC entered into an agreement, effective July 30, 2021, to jointly develop and commercialize KKC's potential first-in-class, phase 3-ready anti-OX40 fully human monoclonal antibody in development for the treatment of atopic dermatitis, with potential in other autoimmune diseases.

Teneobio acquisition

- On October 19, 2021, Amgen completed its acquisition of Teneobio, a privately held, clinical-stage biotechnology company developing a new class of biologics called human heavy-chain antibodies, which are single-chain antibodies composed of the human heavy-chain domain, for $900 million as well as future contingent milestone payments potentially worth up to an additional $1.6 billion upon the achievement of certain developmental and regulatory events.

Products/Pipeline

Inflammation

Otezla

- In December 2021, we announced that the FDA had approved the expanded indication for Otezla for the treatment of adult patients with plaque psoriasis, who are candidates for phototherapy or systemic therapy, across all severities.

TEZSPIRE

- In December 2021, we and AstraZeneca announced that the FDA had approved TEZSPIRE for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Oncology/Hematology

LUMAKRAS/LUMYKRAS

- In May 2021, we announced that the FDA had approved LUMAKRAS for the treatment of adult patients with KRAS *G12C*–mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least one prior systemic therapy. LUMAKRAS received accelerated approval based on ORR and DoR. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial or trials.
- In January 2022, we announced that the EC had granted conditional marketing authorization for LUMYKRAS for the treatment of adults with advanced NSCLC with KRAS G12C mutation and who have progressed after at least one prior line of systemic therapy. We also announced that LUMAKRAS had been approved in Japan for the treatment of KRAS G12C-mutated positive, unresectable, advanced and/or recurrent NSCLC that has progressed after systemic anticancer therapy.

KYPROLIS

- In December 2021, we announced that the FDA had approved the expansion of the KYPROLIS prescribing information to include its use in combination with DARZALEX FASPRO (daratumumab and hyaluronidase-fihj) and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.

Operations

New manufacturing facilities

We announced plans to expand our United States–based manufacturing footprint.

- In August 2021, we announced plans to build a drug substance plant in North Carolina that will increase our manufacturing network capacity to reliably supply more medicines for patients.
- In November 2021, we broke ground to build an advanced assembly and packaging plant in Ohio. The new facility will assemble and package vials and syringes to support the growing demand for our medicines.

We expect that both of these facilities will be built faster and at lower cost than traditional plants. Once completed, both will also utilize cutting-edge technologies to be more efficient and environmentally friendly than traditional plants.

COVID-19 pandemic

A novel strain of coronavirus (SARS-CoV-2, or severe acute respiratory syndrome coronavirus 2, causing COVID-19) was declared a global pandemic by the World Health Organization on March 11, 2020. Since the onset of the pandemic in 2020, we have been closely monitoring the pandemic's effects on our global operations. To date, we have not experienced disruptions to or shortages of our supply of medicines. We continue to take appropriate steps to minimize risks to our employees. Employee access to company facilities has been in accordance with applicable government health and safety protocols and guidance issued in response to the COVID-19 pandemic. The pandemic has shifted how we work as an organization and in the fourth quarter of 2021, we enabled our U.S. based workforce to return to the workplace for work that benefits from face-to-face interaction, while maintaining appropriate safety measures to ensure staff well-being. For further discussion, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview, Selected Financial Information and Results of Operations. For a discussion of the risks presented by the COVID-19 pandemic to our results, see Risk Factors in Item 1A.

Marketing, Distribution and Selected Marketed Products

The largest concentration of our sales and marketing forces is based in the United States and Europe. In recent years, we have expanded the commercialization and marketing of our products into other geographic territories, including China and Japan and other parts of Asia, the Middle East and Latin America. This expansion has occurred, and is expected to continue to occur, by establishing our own affiliates, by acquiring existing third-party businesses or product rights or by collaborating with third parties. See Business Relationships for our significant alliances. Whether we use our own sales and marketing forces or a third party's services varies across these markets. Such use typically depends on several factors, including the nature of entry into the new market, the size of an opportunity and operational capabilities. Together with our collaborators, we market our products to healthcare providers, including physicians or their clinics, dialysis centers, hospitals and pharmacies.

In the United States, substantially all of our sales are to pharmaceutical wholesale distributors, which are the principal means of distributing our products to healthcare providers. We also market certain products through direct-to-consumer channels, including print, television and online media. For further discussion, see Government Regulation—Regulation in the United States—Regulation of Product Marketing and Promotion. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country. In the Asia Pacific region, we also sell our products in partnership with other companies, including BeiGene, Daiichi Sankyo, KKC and Takeda.

Our product sales to three large wholesalers, McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., each individually accounted for more than 10% of total revenues for each of the years 2021, 2020 and 2019. On a combined basis, these wholesalers accounted for 82%, 83% and 81% of worldwide gross revenues for 2021, 2020 and 2019, respectively. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

Our products are marketed around the world, with the United States as our largest market. The following chart shows our product sales by principal product, and the table below (dollar amounts in millions) shows product sales by geography for the years 2021, 2020 and 2019.

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	2021		2020		2019	
Product Sales by Geography:						
U.S.	$ 17,286	71 %	$ 17,985	74 %	$ 16,531	74 %
ROW	7,011	29 %	6,255	26 %	5,673	26 %
Total	$ 24,297	100 %	$ 24,240	100 %	$ 22,204	100 %

ENBREL

We market ENBREL, a tumor necrosis factor blocker, in the United States and Canada. ENBREL was launched in 1998 and is used primarily in indications for the treatment of adult patients with moderately to severely active rheumatoid arthritis, patients with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and patients with active psoriatic arthritis.

Prolia

We market Prolia in many countries around the world. Prolia contains the same active ingredient as XGEVA but is approved for different indications, patient populations, doses and frequencies of administration. Prolia was launched in the United States and Europe in 2010. In the United States, it is used primarily in the indication for the treatment of postmenopausal women with osteoporosis at high risk of fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or in patients who have failed or are intolerant to other available osteoporosis therapy. In Europe, Prolia is used primarily for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Otezla

We market Otezla, a small molecule that inhibits PDE4, in many countries around the world. Otezla was acquired from BMS in November 2019 after their acquisition of Celgene. Otezla is an oral therapy approved for the treatment of adult patients with plaque psoriasis across all severities for whom phototherapy or systemic therapy is appropriate, patients with active psoriatic arthritis and patients with oral ulcers associated with Behçet's disease. In Europe, Otezla is approved for second-line use in the treatment of psoriatic arthritis and psoriasis and for patients with oral ulcers associated with Behçet's disease who are candidates for systemic therapy.

XGEVA

We market XGEVA in many countries around the world. XGEVA was launched in 2010 and is used primarily in the indication for prevention of SREs (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumors and multiple myeloma.

Neulasta

We market Neulasta, a pegylated protein based on the filgrastim molecule, primarily in the United States and Europe. Neulasta was launched in 2002 and is used primarily in the indication to help reduce the chance of infection due to a low white blood cell count in patients with certain types of cancer (nonmyeloid) who receive anticancer medicines (chemotherapy) that can cause fever and a low blood cell count. In 2015, the Neulasta Onpro kit became available in the United States. The Neulasta Onpro kit provides physicians the opportunity to initiate administration of Neulasta on the same day as chemotherapy, with drug delivery of the recommended dose of Neulasta at home the day after chemotherapy, thereby saving the patient a trip back to the doctor.

Aranesp

We market Aranesp primarily in the United States and Europe. It was launched in 2001 and is indicated to treat a lower-than-normal number of red blood cells (anemia) caused by CKD in both patients on dialysis and patients not on dialysis. Aranesp is also indicated for the treatment of anemia due to concomitant myelosuppressive chemotherapy in certain patients with nonmyeloid malignancies and when chemotherapy will be used for at least two months after starting Aranesp.

Repatha

We market Repatha, a PCSK9 inhibitor, in many countries around the world. Repatha was launched in 2015 and is indicated to reduce the risks of myocardial infarction, stroke and coronary revascularization in adults with established CV disease. Repatha is also indicated to reduce LDL-C in adults with primary hyperlipidemia, including HeFH; in pediatric patients aged 10 years and older with HeFH; and in adults and pediatric patients aged 10 years and older with HoFH.

KYPROLIS

We market KYPROLIS primarily in the United States and Europe. KYPROLIS was launched in 2012 and is indicated in combination with (i) dexamethasone, (ii) lenalidomide plus dexamethasone and (iii) DARZALEX plus

dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. It is also approved as a single agent for patients with relapsed or refractory multiple myeloma who have received one or more previous therapies.

Nplate

We market Nplate in many countries around the world. Nplate was launched in 2008 and is indicated to treat thrombocytopenia in patients with chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.

Other Marketed Products

We also market a number of other products in various markets worldwide, including MVASI, Vectibix, KANJINTI, EVENITY, EPOGEN, BLINCYTO, AMGEVITA, Aimovig, Parsabiv, NEUPOGEN, LUMAKRAS/ LUMYKRAS, Sensipar/Mimpara, AVSOLA, RIABNI and TEZSPIRE.

Patents

The following table lists our outstanding material patents for the indicated product by territory, general subject matter and latest expiry date. Certain of the European patents are subjects of supplemental protection certificates that provide additional protection for the products in certain European countries beyond the dates listed in the table. See footnotes to the patent table below.

One or more patents with the same or earlier expiry dates may fall under the same general subject matter and are not listed separately.

Product	Territory	General subject matter	Expiration
Enbrel® (etanercept)	U.S.	Methods of treatment using aqueous formulations	6/8/2023
	U.S.	Formulations	10/19/2037
	U.S.	Fusion protein and pharmaceutical compositions	11/22/2028
	U.S.	DNA encoding fusion protein and methods of making fusion protein	4/24/2029
Prolia®/XGEVA® (denosumab)	U.S.	Methods of treatment	6/25/2022
	U.S.	Nucleic acids encoding RANKL antibodies and methods of producing RANKL antibodies	11/30/2023
	U.S.	RANKL antibodies, including sequences	2/19/2025
	Europe	RANKL antibodies, including sequences(1)	6/25/2022
Otezla® (apremilast)	U.S.	Compositions and compounds	2/16/2028
	U.S.	Crystalline form	12/9/2023
	U.S.	Methods of treatment(2)	5/29/2034
	Europe	Compositions, compounds and methods of treatment(1)	3/20/2023
Aranesp® (darbepoetin alfa)	U.S.	Glycosylation analogs of erythropoietin proteins	5/15/2024
KYPROLIS® (carfilzomib)	U.S.	Compositions and compounds	12/7/2027
	U.S.	Methods of treatment	4/14/2025
	U.S.	Methods of making	5/8/2033
	Europe	Compositions, compounds and methods of treatment(1)	12/7/2025
Repatha® (evolocumab)	U.S.	Antibodies(3)	10/25/2029
	U.S.	Methods of treatment	10/8/2030
	Europe	Compositions(1)	8/22/2028
	Europe	Methods of treatment	5/10/2032
	Europe	Formulation	5/3/2033
Nplate® (romiplostim)	U.S.	Formulation	2/12/2028
	Europe	Thrombopoietic compounds(1)	10/22/2019
	Europe	Formulation	4/20/2027
Vectibix® (panitumumab)	Europe	Human monoclonal antibodies to epidermal growth factor receptor(1)	5/5/2018
EVENITY® (romosozumab-aqqg)	U.S.	Antibodies(3)	4/25/2026
	U.S.	Methods of treatment(3)	1/11/2029
	U.S.	Formulation and methods of using formulation	5/11/2031
	Europe	Antibodies(1)	4/28/2026
	Europe	Methods of treatment	4/18/2032
	Europe	Formulation and methods of using formulation	5/11/2031
BLINCYTO® (blinatumomab)	U.S.	Pharmaceutical compositions and bifunctional polypeptides	4/6/2030
	U.S.	Method of administration	9/28/2027
	Europe	Bifunctional polypeptides(1)	11/26/2024
	Europe	Method of administration	11/6/2029

Product	Territory	General subject matter	Expiration
Aimovig® (erenumab-aooe)	U.S.	CGRP receptor antibodies	5/17/2032
	U.S.	Methods of treatment	4/22/2036
	Europe	CGRP receptor antibodies[1]	12/18/2029
	Europe	Methods of treatment	8/10/2035
Parsabiv® (etelcalcetide)	U.S.	Compound and pharmaceutical composition	2/7/2031
	U.S.	Formulation	6/27/2034
	U.S.	Methods of making	8/9/2035
	Europe	Compound and pharmaceutical composition[1]	7/29/2030
	Europe	Formulation	6/27/2034
LUMAKRAS® / LUMYKRAS™(sotorasib)	U.S.	Compounds and pharmaceutical compositions	5/21/2038
	U.S.	Crystalline form, pharmaceutical compositions and methods of treatment	5/20/2040
	Europe	Compounds, pharmaceutical compositions and methods of treatment	5/21/2038
TEZSPIRE™ (tezepelumab-ekko)	U.S.	Polypeptides[3]	2/3/2029
	U.S.	Methods of treatment	8/23/2038
	Europe	Polypeptides	9/9/2028

(1) A European patent with this subject matter may also be entitled to supplemental protection in one or more countries in Europe, and the length of any such extension will vary by country. For example, supplementary protection certificates have been issued related to the indicated products for patents in at least the following countries:

- denosumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2025
- apremilast — Italy, Spain and the United Kingdom expiring in 2028
- carfilzomib — France, Germany, Italy, Spain and the United Kingdom expiring in 2030
- evolocumab — France, Spain and the United Kingdom, expiring in 2030
- romiplostim — France, Germany, Italy, Spain and the United Kingdom, expiring in 2024
- panitumumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2022
- romosozumab — France, Italy and Spain, expiring in 2031
- blinatumomab — France, Italy and Spain, expiring in 2029
- erenumab — France, Italy and Spain, expiring in 2033
- etelcalcetide — France, Germany, Italy, Spain and the United Kingdom, expiring in 2031

(2) U.S. Patent No. 10,092,541 was held invalid by the New Jersey District Court. We disagree with the court's holding and we are in the process of appealing this judgment. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements, Amgen Inc. vs. Sandoz Inc., et al.

(3) A patent with this subject matter may be entitled to patent term extension in the United States.

Competition

We operate in a highly competitive environment. A number of our marketed products are indicated for disease areas in which other products or treatments are currently available or are being pursued by our competitors through R&D activities. Additionally, some competitor-marketed products target the same genetic pathways as our recently launched marketed products or are currently in development. This competition could impact the pricing and market share of our products. We continue to pursue ways of increasing the value of our medicines through innovations during their life cycles, which can include expanding the disease areas for which our products are indicated and finding new methods to make the delivery of our medicines easier and less costly. Such activities can offer important opportunities for differentiation. For example, we market the Neulasta Onpro kit, which provides physicians the opportunity to initiate administration of the recommended dose of Neulasta on the same day as chemotherapy, with drug delivery at home the day after chemotherapy, thereby saving the patient a trip back to the doctor. We plan to continue pursuing innovation efforts to strengthen our competitive position. Such position may be based on, among other things, safety, efficacy, reliability, availability, patient convenience, delivery devices, price, reimbursement, access to and timing of market entry and patent position and expiration.

Certain of the existing patents on our principal products have expired, and we face new and increasing competition, including from biosimilars and generics. A biosimilar is another version of a biological product for which marketing approval is sought or has been obtained based on a demonstration that it is "highly similar" to the original reference product. We have experienced adverse effects from biosimilar competition on our originator product sales. Companies have launched biosimilar versions of EPOGEN, NEUPOGEN and Neulasta and have approved biosimilars for ENBREL. Once multiple biosimilar versions of one of our originator products have launched, competition has intensified rapidly, resulting in greater net price declines for both reference and biosimilar products, and a greater effect on product sales. See also Government Regulation—Regulation in the United States—Approval of Biosimilars. Although competitor biosimilars compete on price, we believe many patients, providers and payers will continue to place high value on the reputation, supply reliability and safety of our products. As additional biosimilar competitors come to market, we will continue to leverage our global experience to distinguish against both branded and biosimilar competition.

We also have our own biosimilar products both in the United States and outside of U.S. markets that are competing against branded and biosimilar versions of our competitors' products. In 2019, Amgen launched MVASI, a biosimilar to Avastin, and KANJINTI, a biosimilar to Herceptin; and in 2018, Amgen launched AMGEVITA, a biosimilar to Humira in ex-U.S. markets. We have also received FDA approval of AMJEVITA, a biosimilar to Humira for the U.S. market, and plan to launch in the United States in January 2023. In 2020, we launched AVSOLA, a biosimilar to Remicade; and in January 2021, we launched RIABNI, a biosimilar to Rituxan. We expect additional biosimilar competition against both our branded and biosimilar products in the future across markets.

Although most of our products are biologics, some are small molecule products. Because the FDA approval process permits generic manufacturers to rely on the safety and efficacy data of the innovator product rather than having to conduct their own costly and time-consuming clinical trials, generic manufacturers can often develop and market their competing versions of our small molecule products at much lower prices. For example, following loss of exclusivity of patents directed to cinacalcet, the active ingredient in our small molecule calcimimetic Sensipar, we lost a significant share of the market and corresponding revenues in a very short period of time. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

The introduction of new products, the development of new processes or technologies by competitors or the emergence of new information about existing products may result in (i) increased competition for our marketed products, even for those protected by patents and/or (ii) reductions in the prices we receive from selling our products. In addition, the development of new treatment options or standards of care may reduce the use of our products or may limit the utility and application of ongoing clinical trials of our product candidates. (As used in this document, the term *clinical trials* may include prospective clinical trials, observational studies, registries and other studies.) See Item 1A. Risk Factors—*Our products face substantial competition and our product candidates are also likely to face substantial competition* and Item 1A. Risk Factors—*We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future*.

The following table reflects our significant competitors and is not exhaustive.

Product	Territory	Competitor-marketed product	Competitors
ENBREL	U.S. & Canada	HUMIRA	AbbVie
	U.S.	Xeljanz	Pfizer Inc.
	U.S. & Canada	RINVOQ	AbbVie
Prolia	U.S. & Europe	Alendronate, raloxifene and zoledronate generics	Various
Otezla	U.S. & Europe	HUMIRA†	AbbVie
	U.S. & Europe	Cosentyx	Novartis
	U.S. & Europe	Taltz	Lilly
	U.S. & Europe	Tremfya	Janssen(1)
	U.S. & Europe	Skyrizi(2)	AbbVie
	U.S. & Europe	Methotrexate generics	Various
XGEVA	U.S. & Europe	Zoledronate generics	Various
Neulasta(3)	U.S.	UDENYCA	Coherus BioSciences, Inc.
	U.S.	Fulphila	Mylan Institutional Inc.
	U.S. & Europe	Filgrastim biosimilars	Various
Aranesp	U.S.	PROCRIT(4)	Janssen(1)
	U.S. & Europe	Epoetin alfa biosimilars	Various
Repatha	U.S. & Europe	PRALUENT	Regeneron Pharmaceuticals, Inc. Sanofi
KYPROLIS(5)	U.S.	VELCADE	Millennium Pharmaceuticals, Inc.(6)
	U.S. & Europe	REVLIMID	Celgene(7)
	U.S. & Europe	POMALYST/IMNOVID	Celgene(7)
	U.S. & Europe	DARZALEX	Janssen(1)
Nplate	U.S. & Europe	PROMACTA/ REVOLADE	Novartis

† Approved biosimilars available in Europe and Canada.

(1) A subsidiary of J&J.

(2) Dermatology only.

(3) Other biosimilars under regulatory review in the United States and Europe.

(4) PROCRIT competes with Aranesp in supportive cancer care and predialysis settings.

(5) KYPROLIS is facing increased competition from several recently approved products.

(6) A subsidiary of Takeda.

(7) A subsidiary of BMS.

Reimbursement

Sales of our principal products are dependent on the availability and extent of coverage and reimbursement from third-party payers. In many markets around the world, these payers, including government health systems, private health insurers and other organizations, remain focused on reducing the cost of healthcare; and their efforts have intensified as a result of rising healthcare costs, economic pressures and broader challenges generated by the COVID-19 pandemic. Drugs remain heavily scrutinized for cost containment. As a result, payers are becoming more restrictive regarding the use of biopharmaceutical products and are scrutinizing the prices of these products while

requiring a higher level of clinical evidence to support the benefits such products bring to patients and the broader healthcare system. These pressures become intensified when our products become subject to competition, including from biosimilars.

In the United States, healthcare providers and other entities such as pharmacies and PBMs are reimbursed for covered services and products they deliver through both private-payer and government healthcare programs such as Medicare and Medicaid. We provide negotiated rebates to healthcare providers, private payers, government payers and PBMs. In addition, we are required to (i) provide rebates or discounts on our products that are reimbursed through certain government programs, including Medicare and Medicaid, and (ii) provide discounts to qualifying healthcare providers under the federal 340B Drug Pricing Program.

Both private and some government payers use formularies to manage access to and utilization of drugs. A drug's inclusion and favorable positioning on a formulary are essential to ensure patients have access to a particular drug. Even when access is available, some patients abandon their prescriptions for economic reasons. Payers continue to institute cost reduction and containment measures that lower drug utilization and/or spending altogether and/or shift a greater portion of the costs to patients. Such measures include, but are not limited to, more-limited benefit plan designs, higher patient co-pays or coinsurance obligations, limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs), stricter utilization management criteria before a patient may get access to a drug, higher-tier formulary placement that increases the level of patient out-of-pocket costs and formulary exclusion, which effectively encourages patients and providers to seek alternative treatments or pay 100% of the cost of a drug. The use of such measures by PBMs and insurers has continued to intensify and has thereby limited Amgen product usage and sales. Furthermore, during the past few years, many PBMs and insurers have consolidated, resulting in a smaller number of PBMs and insurers overseeing a large portion of total covered lives in the United States. As a result, PBMs and insurers have greater market power and negotiating leverage to mandate stricter utilization criteria and/or exclude drugs from their formularies in favor of competitor drugs or alternative treatments. In highly competitive treatment markets such as the markets for ENBREL, Otezla, Repatha and Aimovig, PBMs are also able to exert negotiating leverage by requiring incremental rebates from manufacturers in order for them to gain and/or maintain their formulary position.

In addition to market actions taken by private and government payers in the United States, policy makers in both of the major U.S. political parties are pursuing policies to lower drug costs. Potential policies cover a wide range of areas, including allowing the importation of drugs from other countries; instituting IRP schemes, which would set the prices of certain drugs based on those available in other countries; implementing policies that in effect would require manufacturers to accept government-set prices for certain drugs, with price ceilings based on a domestic reference-pricing scheme; redesigning the Medicare Part D benefit so as to establish a cap on patient out-of-pocket costs, paired with new requirements that manufacturers cover a share of the costs of Part D drugs; stipulating penalties if drug price benchmarks rise faster than inflation; increasing transparency in drug pricing; and using third-party value assessments to determine drug prices. Examples of such policies include, but are not limited to, the previous Administration's November 2020 interim final rule, which attempts to institute an MFN IRP model in Medicare Part B and a final rule instituting rebate reform in Medicare Part D. Both of the resulting rules are being challenged in court and have not yet been implemented. Further, although CMS withdrew the MFN IRP, policy makers continue to express strong interest in policies to address drug pricing. See Item 1A. Risk Factors—*Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability*. The Infrastructure Investment and Jobs Act signed into law on November 15, 2021, delays implementation of the rebate reform rule until 2026 and requires manufacturers of certain Part B–covered drugs packaged in single-use containers to give refunds to the government starting in 2023 for discarded amounts. Although the direction of drug-pricing-policy reforms remains unclear at this time, Congress is continuing to consider prescription-drug-pricing reforms, including legislative proposals for a number of the concepts discussed above (including a full repeal of the prior Administration's Part D rebate reform rule).

In many countries other than the United States, government-sponsored healthcare systems are the primary payers for drugs and biologics. With increasing budgetary constraints and/or difficulty in understanding the value of medicines, governments and payers in many countries are applying a variety of measures to exert downward price pressure. These measures can include mandatory price controls, price referencing, therapeutic-reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage and government-mandated price cuts. In this regard, many countries have health technology assessment organizations that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies; and these organizations are expanding in both established and emerging markets. Many countries also limit coverage to populations narrower than those specified on our product labels or impose volume caps to limit utilization. We expect that countries will continue taking aggressive actions to seek to reduce expenditures on drugs and biologics. Similarly, fiscal constraints

may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies. The EU is currently undergoing a review and possible revision of its pharmaceutical legislation, scheduled to conclude at the end 2022. There is a risk that this review will lead to proposals that may reduce intellectual property protection for new products, as well as change the reimbursement and regulatory landscape in ways that are difficult to predict at this point.

The dynamics and developments discussed above create pressures on the pricing and potential usage of our products and on the industry. Given the diverse interests in play between payers, biopharmaceutical manufacturers, policy makers, healthcare providers and independent organizations, if and whether the parties involved can achieve alignment on the matters discussed above remain unclear, and the outcome of any such alignment is difficult to predict. We remain focused on pricing our products responsibly and delivering breakthrough treatments for unmet medical needs. Amgen is committed to working with the entire healthcare community to ensure continued innovation and to facilitate patient access to needed medicines. We do this by:

- investing billions of dollars annually in R&D;
- pricing our medicines to reflect the value they provide;
- developing more affordable therapeutic choices in the form of high-quality and reliably supplied biosimilars;
- partnering with payers to share risk and accountability for health outcomes;
- providing patient support and education programs;
- helping patients in financial need access our medicines; and
- working with policy makers, patients and other stakeholders to establish a sustainable healthcare system with access to affordable care and in which patients and their healthcare professionals are the primary decision makers.

See Item 1A. Risk Factors—*Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability* and Item 1A. Risk Factors—*Guidelines and recommendations published by various organizations can reduce the use of our products.*

Manufacturing, Distribution and Raw Materials

Manufacturing

We believe we are a leader in the manufacture of biologics and that our manufacturing capabilities represent a competitive advantage. The products we manufacture consist of both biologics and small molecule drugs. The majority of our products are biologics that are produced in living cells and that are inherently complex due to naturally occurring molecular variations. Highly specialized knowledge and extensive process and product characterization are required to transform laboratory-scale processes into reproducible commercial manufacturing processes. Further, our expertise in the manufacture of biologics positions us well for leadership in the global biosimilars market. For additional information regarding manufacturing facilities, see Item 2. Properties.

We have been innovating our manufacturing facilities designed to extend our manufacturing advantage by optimizing our manufacturing network and/or by mitigating risks while continuing to ensure adequate supply of our products. For example, our licensed next-generation biomanufacturing plant operating in Singapore, and our recently FDA approved facility in West Greenwich, Rhode Island, incorporate multiple innovative technologies into a single facility. Next-generation biomanufacturing plants require smaller manufacturing footprints and offer greater environmental benefits, including reduced consumption of water and energy and lower levels of carbon emissions. Within such plants, the equipment is portable and smaller, which provides greater flexibility and speed in the manufacture of different medicines simultaneously. This enables Amgen to respond to changing demands for its medicines with increased agility. The Singapore site also has a plant that has been approved by several agencies, including the FDA and EMA, to produce small molecule drugs for commercial manufacturing.

Our internal manufacturing network has commercial production capabilities for bulk manufacturing, formulation, fill, finish, tableting and device assembly. These activities are performed within the United States and its territories in our Puerto Rico, Rhode Island and California facilities as well as internationally in our Ireland, Netherlands and Singapore facilities. In addition, we use third-party contract manufacturers to supplement the capacity or capability of our commercial manufacturing network.

To support our clinical trials, we manufacture product candidates primarily at our California facilities. We also use third-party contract manufacturers to supplement the capacity or capability of our overall clinical manufacturing network.

See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

Distribution

We operate distribution centers in Puerto Rico, Kentucky, California and the Netherlands for worldwide distribution of the majority of our commercial and clinical products. We also use third-party distributors to supplement distribution of our products worldwide.

Other

In addition to the manufacturing and distribution activities noted above, each of our manufacturing locations includes key manufacturing support functions such as quality control, process development, engineering, procurement, production scheduling and warehousing. Certain of those manufacturing and distribution activities are highly regulated by the FDA as well as international regulatory agencies. See Government Regulation—Regulation in the United States—Regulation of Manufacturing Standards.

Manufacturing Initiatives

As discussed above, we have been expanding capacity and advancing new innovations with multiple ongoing projects.

Our next-generation biomanufacturing plant at our West Greenwich, Rhode Island, campus, the first of its kind in the United States, received FDA approval in January 2022. This plant expands our capacity to manufacture certain products for U.S. and global markets, as we receive regulatory approval in those markets.

We initiated projects in 2019 to expand our clinical and commercial manufacturing capabilities in Thousand Oaks, California, which we have completed.

In August 2021, we initiated a project to build a new multi-product drug substance manufacturing facility in Holly Springs, North Carolina. The new plant will support both traditional stainless steel-fed batch manufacturing and next-generation single-use technologies, allowing flexibility in the production of multiple products in one plant.

In November 2021, we broke ground for our newest biomanufacturing plant located in New Albany, Ohio. This final product assembly and packaging plant will support the growing demand for Amgen's medicines in the United States and will use state-of-the-art technologies.

See Item 1A. Risk Factors—*Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

Raw Materials and Medical Devices

Certain raw materials, medical devices (including companion diagnostics) and components necessary for the commercial and/or clinical manufacturing of our products are provided by and are the proprietary products of unaffiliated third-party suppliers, certain of which may be our only sources for such materials. We currently attempt to manage the risk associated with such suppliers by means of inventory management, relationship management and evaluation of alternative sources when feasible. We also monitor the financial condition of certain suppliers and their ability to supply our needs. See Item 1A. Risk Factors—*We rely on third-party suppliers for certain of our raw materials, medical devices and components.*

We perform various procedures to help authenticate the sources of raw materials, including intermediary materials used in the manufacture of our products; the procedures include verification of country of origin and are incorporated into the manufacturing processes we and our third-party contract manufacturers perform.

To better ensure supply, Amgen has a risk mitigation strategy that uses a combination of methods, including multiple sources or backup inventory of critical raw materials. In response to the COVID-19 pandemic and as part of our ongoing business continuity efforts, we continue to closely monitor our inventory levels and have taken additional measures to mitigate against raw material supply interruption. See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

Government Regulation

Regulation by government authorities in the United States and other countries is a significant factor in the production and marketing of our products and our ongoing R&D activities. To clinically test, manufacture and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards

established by various regulatory bodies. Compliance with these standards is complex, and failure to comply with any of these standards can result in significant implications. See Item 1A. Risk Factors for a discussion of factors, including global regulatory implications, that can adversely impact our development and marketing of commercial products.

Regulation in the United States

In the United States, the Public Health Service Act; the FDCA; and the regulations promulgated thereunder as well as other federal and state statutes and regulations govern, among other things, the production, research, development, testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising, promotion and distribution of our products in addition to the reporting of certain payments and other transfers of value to healthcare professionals and teaching hospitals.

Clinical Development and Product Approval. Drug development in our industry is complex, challenging and risky, and failure rates are high. Product development cycles are typically very long—approximately 10 to 15 years from discovery to market. A potential new medicine must undergo many years of preclinical and clinical testing to establish its safety and efficacy for use in humans at appropriate dosing levels and with an acceptable risk–benefit profile. We continue to work toward reducing cycle times by applying our expertise in human genetics and innovation in technology, clinical trials and real-world evidence.

After laboratory analysis and preclinical testing in animals, we file an IND with the FDA to begin human testing. Typically, we undertake an FDA-designated three-phase human clinical testing program.

- In phase 1, we conduct small clinical trials to investigate the safety and proper dose ranges of our product candidates in a small number of human subjects.
- In phase 2, we conduct clinical trials to investigate side-effect profiles and the efficacy of our product candidates in a patient population larger than phase 1 but still relatively small, who have the disease or condition under study.
- In phase 3, we conduct clinical trials to investigate the short- and long-term safety and efficacy of our product candidates, compared to commonly used treatments, in a large number of patients who have the disease or condition under study.

The FDA monitors the progress of each trial conducted under an IND and may, at its discretion, reevaluate, alter, suspend or terminate the testing based on data accumulated to that point and the FDA's risk–benefit assessment with regard to the patients enrolled in the trial. The results of preclinical and clinical trials are submitted to the FDA in the form of either a BLA for biologic products or a New Drug Application for small molecule products. We are not permitted to market or promote a new product until the FDA has approved our marketing application.

Approval of Biosimilars. The ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. The pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on the nonclinical-trial and clinical-trial data of an originator product to which the biosimilar has been demonstrated to be "highly similar" and to have no clinically meaningful differences with regard to safety, purity and potency. The relevance of demonstrating "similarity" is that in many cases, biosimilars can be brought to market without conducting the full suite of clinical trials typically required of originators, because risk–benefit has previously been established. To preserve incentives for future innovation, the law establishes a period of exclusivity for originators' products, which in general prohibits biosimilars from gaining FDA approval based in part on reliance on or reference to the originator's data in their application to the FDA for 12 years after initial FDA approval of the originator product. The law does not change the duration of patents granted on biologic products. As part of the implementation of the abbreviated approval pathway for biosimilars, the FDA released a number of guidance documents, some of which remain in draft form.

Regulation of Product Marketing and Promotion. The FDA regulates the marketing and promotion of drug products. Our product promotions for approved product indications must comply with the statutory standards of the FDCA and the FDA's implemented regulations and guidance. The FDA's review of marketing and promotional activities encompasses but is not limited to direct-to-consumer advertising, healthcare-provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA may also review industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. The FDA may take enforcement action against a company for promoting unapproved uses of a product or for other violations of the FDA's advertising and labeling laws and regulations. Enforcement action may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with the FDA's regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators.

Additionally, as described below, such failure may lead to additional liability under U.S. healthcare fraud and abuse laws.

Regulation of Manufacturing Standards. The FDA regulates and inspects the equipment, facilities, laboratories and processes used in the manufacturing and testing of products prior to granting approval to market products. If after receiving approval from the FDA we make a material change in manufacturing equipment, location or process, additional regulatory review may be required. We also must adhere to current Good Manufacturing Practice regulations and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA conducts regular, periodic visits to reinspect our equipment, facilities, laboratories and processes following an initial approval.

Regulation of Combination Products. Combination products are defined by the FDA as products composed of two or more regulated components (e.g., a biologic and/or drug and a device). Biologics/drugs and devices each have their own regulatory requirements, and combination products may have additional requirements. A number of our marketed products meet this definition and are regulated under this framework, and we expect that a number of our pipeline product candidates will be evaluated for regulatory approval under this framework as well.

Regulation outside the United States

In EU countries as well as in the United Kingdom, Switzerland, Canada, Australia and Japan, regulatory requirements and approval processes are similar in principle to those in the United States.

In the EU, there are currently two potential tracks for seeking marketing approval for a product not authorized in any EU member state: a decentralized procedure and a centralized procedure. In the *decentralized procedure*, identical applications for marketing authorization are submitted simultaneously to the national regulatory agencies. Regulatory review is led by one member state (the reference-member state), and its assessment—based on safety, quality and efficacy—is reviewed and approved (assuming there are no concerns that the product poses a serious risk to public health) by the other member states from which the applicant is seeking approval (the concerned-member states). The decentralized procedure leads to a series of single national approvals in all relevant countries. In the *centralized procedure*, which is required of all products derived from biotechnology, a company submits a single Marketing Authorisation Application to the EMA, which conducts an evaluation of the dossier, drawing upon its scientific resources across Europe. If the drug product is proven to fulfill requirements for quality, safety and efficacy, the EMA's CHMP adopts a positive opinion, which is transmitted to the EC for final decision on granting of the marketing authorization. Even though the EC generally follows the CHMP's opinion, it is not bound to do so. Subsequent commercialization is enabled by country-by-country reimbursement approval.

In the EU, biosimilars are approved under a specialized pathway of the centralized procedure. As with the U.S. pathway, an applicant seeks and obtains regulatory approval for a biosimilar once the data exclusivity period for the original reference product has expired, relying in part on the data submitted for the originator product together with data evidencing that the biosimilar is "highly similar" with regard to quality, safety and efficacy to the original reference product authorized in the European Economic Area.

Other countries such as Russia, Turkey and those in Latin America and the Middle East have review processes and data requirements similar to those of the EU and in some cases can rely on prior marketing approval from U.S. or EU regulatory authorities. The regulatory process in these countries may include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements.

In Asia Pacific, a number of countries such as China, Japan, South Korea and Taiwan may require local clinical-trial data for bridging purposes as part of the drug registration process in addition to global clinical trials, which can add to overall drug development and registration timelines. In most of the Asian markets, registration timelines depend on marketing approval in the United States or the EU. In some markets in Asia, such as China, Indonesia and Thailand, regulatory timelines can be less predictable. The regulatory process may also include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements. Countries such as Australia and Japan have more-mature systems that would allow for submissions under more-competitive time frames. With regard to biosimilars, several of these countries have pathways to register biosimilars (e.g., Australia, India, Singapore, South Korea and Taiwan), and biosimilar products are already present on the markets (e.g., Australia and South Korea).

In some countries, such as Japan and those in the EU, medical devices may be subject to regulatory regimes whereby manufacturers must establish that their medical devices conform to essential requirements set out in the law for the particular device category. For example, in the EU, with limited exceptions, medical devices placed on the market must bear the Conformité Européenne marking to indicate their conformity with legal requirements.

Postapproval Phase

After approval, we continue to monitor adverse events and product complaints reported following the use of our products through routine postmarketing surveillance and studies when applicable. We report such events to the appropriate regulatory agencies as required by local regulations for individual cases and aggregate reports. We proactively monitor (according to good pharmacovigilance practices) and ensure the implementation of signal detection, assessment and the communication of adverse events that may be associated with the use of our products. We also proactively monitor product complaints through our quality systems, which includes assessing our drug delivery devices for device complaints, adverse events and malfunctions. We may also be required by regulatory agencies to conduct further clinical trials on our marketed products as a condition of their approval or to provide additional information on safety and efficacy. Health regulators, including the FDA, have authority to mandate labeling changes to products at any point in a product's life cycle based on new safety information or as part of an evolving label change to a particular class of products.

Health regulators, including the FDA, also have authority both before and after approval to require that a company implement a risk management program for a product to ensure that the benefits of the drug outweigh the risks. Each risk management program is unique and varies depending on the specific factors required. In the United States, such a risk management program is known as a REMS; and we currently have REMSs for Prolia, Nplate and BLINCYTO.

Other Regulation

We are also subject to various laws pertaining to healthcare fraud and abuse, including antikickback laws and false-claims laws. Antikickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for or to induce the referral of business, including the purchase or prescribing of a particular drug that is reimbursed by a state or federal program. False-claims laws prohibit knowingly and willingly presenting or causing to be presented for payment to third-party payers (including Medicare and Medicaid) any claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as by the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). Liability under false-claims laws may also arise when violation of certain laws or regulations related to the underlying product (e.g., a violation regarding improper promotional activity or unlawful payments) contributes to the submission of a false claim.

On April 25, 2019, we entered into a settlement agreement with the DOJ and the OIG of the HHS to settle certain allegations related to our support of independent charitable organizations that provide patients with financial assistance to access medicines. Additionally, we entered into a corporate integrity agreement that requires us to both maintain a corporate compliance program and undertake a set of defined corporate integrity obligations for a period of five years. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that in the future, our practices might be further challenged under antikickback or similar laws.

The FCPA prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA arguably includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anticorruption laws and/or regulations. Failure by our employees, agents, contractors, vendors, licensees, partners or collaborators to comply with the FCPA and other anticorruption laws and/or regulations could result in significant civil or criminal penalties.

We are subject to various laws and regulations globally with regard to privacy and data protection. These laws and regulations involve the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environments regarding privacy and data protection are continually evolving and developing because these issues are subjects of increasing amounts of attention in countries globally. For example, we are subject to the EU's GDPR, which became effective on May 25, 2018, the California Consumer Privacy Act of 2018, which became effective on January 1, 2020 and China's Personal Information Protection Law, which became effective on November 1, 2021. Other jurisdictions where we operate have enacted or proposed similar legislation and/or regulations. For example, the Virginia Consumer Data Protection Act and the Colorado Privacy Act are set to become effective on January 1, 2023, and July 1, 2023, respectively. Failure to comply with these laws could result in significant penalties.

Our business has been and will continue to be subject to various other U.S. and foreign laws, rules and regulations. See Reimbursement section above.

Research and Development and Selected Product Candidates

We focus our R&D on novel human therapeutics for the treatment of serious illness. We capitalize on our strengths in human genetics, novel biology and protein engineering. We leverage our biologic expertise and seek to choose the optimal modality for a drug target and disease. And we use cutting-edge science and technology to study subtle biological mechanisms in search of therapies that will improve the lives of those who suffer from diseases.

Our discovery research programs may therefore yield targets that lead to the development of human therapeutics delivered as large molecules, small molecules, other combination modalities or new modalities. We have reshaped our portfolio and have increasingly focused our efforts on human genetics when possible to enhance the likelihood of success.

Since early 2021, COVID-19 global vaccination efforts have been under way to control the pandemic. However, uncertainty remains as to the length of time required for vaccination of a meaningful portion of the population and as to the efficacy of such vaccinations on the trajectory of the pandemic. Challenges to vaccination efforts, new variants and other causes of virus spread may require governments to issue additional restrictions and/or order shutdowns in various geographies. As a result, we expect to see continued volatility for at least the duration of the pandemic as governments respond to current local conditions. With regard to our drug development activities, we are continuously monitoring COVID-19 infection rates, including changes from new variants; we are working to mitigate effects on future study enrollment in our clinical trials; and we are evaluating the impact in all countries where clinical trials occur. We remain focused on supporting our active clinical sites in their providing care for patients and in our providing investigational drug supply.

For the years ended December 31, 2021, 2020 and 2019, our R&D expenses were $4.8 billion, $4.2 billion and $4.1 billion, respectively.

We have major R&D centers in Thousand Oaks and San Francisco, California; Iceland; and the United Kingdom, as well as smaller research centers and development facilities globally. See Item 2. Properties.

Our clinical trial activities are conducted by both our internal staff and third-party contract clinical trial service providers. To increase the number and diversity of patients available for enrollment in our clinical trials, we have opened clinical sites and will continue opening clinical sites and enrolling patients in a number of geographic locations. See Government Regulation—Regulation in the United States—Clinical Development and Product Approval for a discussion of government regulation over clinical development. Also see Item 1A. Risk Factors—*We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.*

Some of our competitors are actively engaged in R&D in areas in which we have products or in which we are developing product candidates or new indications for existing products. For example, we compete with other clinical trials for eligible patients, which may limit the number of available patients who meet the criteria for certain clinical trials. The competitive marketplace for our product candidates is greatly dependent on the timing of entry into the market. Early entry may have important advantages in gaining product acceptance, thereby contributing to a product's eventual success and profitability. Accordingly, we expect that in some cases, the relative speed with which we can develop products, complete clinical testing, receive regulatory approval and supply commercial quantities of a product to the market will be important to our competitive position.

In addition to product candidates and marketed products generated from our internal R&D efforts, we acquire companies, acquire and license certain product and R&D technology rights and establish R&D arrangements with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. In pursuing these R&D arrangements and licensing or acquisition activities, we face competition from other pharmaceutical and biotechnology companies that also seek to license or acquire technologies, product candidates or marketed products from those entities performing the R&D.

The following table shows a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 8, 2022, unless otherwise indicated. Additional product candidate information can be found on our website at www.amgen.com. (The website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.) The information in this section does not include other, nonregistrational clinical trials that we may conduct for purposes other than for submission to regulatory agencies for their approval of a new product indication.

We may conduct nonregistrational clinical trials for various reasons, including to evaluate real-world outcomes or to collect additional safety information with regard to the use of products.

Molecule	Investigational indication
Phase 3 programs	
AMJEVITA	Interchangeability
Bemarituzumab	GEJ adenocarcinoma
BLINCYTO	Ph-negative B-cell precursor Acute lymphoblastic leukemia
EVENITY	Male osteoporosis
KYPROLIS	Weekly dosing for relapsed multiple myeloma
Nplate	Chemotherapy-induced thrombocytopenia
Otezla	Genital psoriasis
Repatha	Cardiovascular disease
TEZSPIRE	Chronic rhinosinusitis with nasal polyps Severe asthma
ABP 654	Investigational biosimilar to STELARA (ustekinumab)
ABP 938	Investigational biosimilar to EYLEA (aflibercept)
ABP 959	Investigational biosimilar to SOLIRIS (eculizumab)
Phase 2 programs	
Efavaleukin alfa	Systemic lupus erythematosus Ulcerative colitis
LUMAKRAS/LUMYKRAS	Advanced colorectal cancer NSCLC monotherapy Other solid tumors with KRAS *G12C* mutations
Olpasiran	Cardiovascular disease
Ordesekimab	Celiac disease
Otezla	Palmoplantar pustulosis
Rozibafusp alfa	Systemic lupus erythematosus
Tarlatamab	Small cell lung cancer
TEZSPIRE	Chronic obstructive pulmonary disease Chronic spontaneous urticaria
AMG 451/KHK 4083	Atopic dermatitis
Phase 1 programs	
Acapatamab	Prostate cancer
Pavurutamab	Multiple myeloma
Tarlatamab	Small-cell lung cancer
AMG 104	Asthma
AMG 119	Small-cell lung cancer
AMG 133	Obesity
AMG 176	Hematologic malignancies
AMG 193	Solid tumors
AMG 199	Metastatic GEJ cancer
AMG 256	Solid tumors
AMG 330	Acute myeloid leukemia
AMG 340	Prostate cancer
AMG 404	Solid tumors
AMG 427	Acute myeloid leukemia
AMG 506	Solid tumors
AMG 509	Prostate cancer
AMG 609	Nonalcoholic steatohepatitis
AMG 650	Solid tumors
AMG 994	Solid tumors

Phase 3	Clinical trials investigate the short- and long-term safety and efficacy of our product candidates, compared to commonly used treatments, in a large number of patients who have the disease or condition under study.
Phase 2	Clinical trials investigate side-effect profiles and efficacy of product candidates in a larger patient population than phase 1, but still relatively small, who have the disease or condition under study.
Phase 1	Clinical trials investigate the safety and proper dose ranges of product candidates in a small number of human subjects.

Phase 3 Product Candidate Program Changes

As of February 2, 2021, we had 13 phase 3 programs. As of February 8, 2022, we continued to have 13 phase 3 programs, as regulatory approvals were received for three programs, four programs initiated phase 3 studies and one program was terminated. These changes are set forth in the following table.

Molecule	Investigational indication	Program change
LUMAKRAS/ LUMYKRAS	NSCLC with KRAS G12C mutations	Approved by the FDA and conditional marketing approval by the EC
Otezla	Mild-to-moderate psoriasis	Approved by the FDA
RIABNI	Non-Hodgkin's lymphoma	Approved by the FDA
AMJEVITA	Interchangeability	Initiated phase 3 study
Bemarituzumab	GEJ adenocarcinoma	Initiated phase 3 study
BLINCYTO	Ph-negative B-cell precursor Acute lymphoblastic leukemia	Initiated phase 3 study
TEZSPIRE	Chronic rhinosinusitis with nasal polyps	Initiated phase 3 study
Otezla	COVID-19	Terminated

Phase 3 Product Candidate Patent Information

The following table describes our composition-of-matter patents that have been issued thus far for our product candidates in phase 3 development that have yet to be approved for any indication in the United States or the EU. Patents for products already approved for one or more indications in the United States or the EU but that are currently undergoing phase 3 clinical trials for additional indications have been previously described. See Marketing, Distribution and Selected Marketed Products—Patents.

Molecule	Territory	General subject matter	Estimated expiration*
Bemarituzumab	U.S.	Polypeptides	2029
	Europe	Polypeptides	2029

* Patent expiration estimates are based on issued patents, which may be challenged, invalidated or circumvented by competitors. The estimates do not include any term adjustments, extensions or supplemental protection certificates that may be obtained in the future and thereby extend these dates. Corresponding patent applications are pending in other jurisdictions. Additional patents may be filed or issued and may provide additional exclusivity for the product candidate or its use.

Phases 3 and 2 Program Descriptions

The following provides additional information about selected product candidates that have advanced into human clinical trials.

AMJEVITA

AMJEVITA is a biosimilar to HUMIRA, which is a monoclonal antibody that inhibits binding of TNF-alpha to cell surface TNF receptor / TNF-alpha.

Bemarituzumab

Bemarituzumab is a monoclonal antibody that inhibits FGFR2b. It is being investigated for the treatment of advanced GEJ adenocarcinoma.

In April 2021, Amgen announced that the FDA had granted Breakthrough Therapy designation for bemarituzumab.

BLINCYTO

BLINCYTO is an anti-CD19 x anti-CD3 BiTE® molecule. It is being investigated in newly diagnosed adults age 40 and older with Ph negative B-Cell precursor ALL.

Efavaleukin alfa

Efavaleukin alfa is an IL-2 mutein Fc fusion protein. It is being investigated for the treatment of systemic lupus erythematosus and ulcerative colitis.

EVENITY

EVENITY is a monoclonal antibody that inhibits the action of sclerostin. It is being evaluated as a treatment for male osteoporosis. EVENITY is being developed in collaboration with UCB.

KYPROLIS

KYPROLIS is a small molecule proteasome inhibitor. It is being investigated for weekly dosing in combinations with lenalidomide and dexamethasone for relapsed multiple myeloma.

In December 2021, we announced that the FDA had approved the expansion of the KYPROLIS prescribing information to include its use in combination with DARZALEX FASPRO (daratumumab and hyaluronidase-fihj) and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.

LUMAKRAS/LUMYKRAS

LUMAKRAS is a KRAS *G12C* small molecule inhibitor. It is being investigated as treatment for a variety of solid tumors, including NSCLC, colorectal cancer and other solid tumor cancers.

In May 2021, we announced that the FDA had approved LUMAKRAS for the treatment of adult patients with KRAS *G12C*–mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least one prior systemic therapy.

In November 2021, we announced that the EMA's CHMP had adopted a positive opinion and recommended conditional marketing authorization of LUMYKRAS, known as LUMAKRAS in the United States, for the treatment of adults with advanced NSCLC with KRAS *G12C* mutation and who have progressed after at least one prior line of systemic therapy.

In January 2022, we announced that the EC had granted conditional marketing authorization for LUMYKRAS for the treatment of adults with advanced NSCLC with KRAS G12C mutation and who have progressed after at least one prior line of systemic therapy. We also announced that LUMAKRAS had been approved in Japan for the treatment of KRAS G12C-mutated positive, unresectable, advanced and/or recurrent NSCLC that has progressed after systemic anticancer therapy.

Nplate

Nplate is a TPO-RA. It is being investigated for the treatment of CIT.

Olpasiran

Olpasiran is an siRNA that lowers lipoprotein(a), also known as Lp(a). It is being investigated in phase 2 for the treatment of atherosclerotic CV disease.

Ordesekimab

Ordesekimab is a monoclonal antibody that inhibits the action of IL-15. It is being investigated for the treatment of celiac disease and is being developed in collaboration with Provention Bio, Inc.

Otezla

Otezla is a small molecule that inhibits PDE4. It is being investigated in phase 3 studies for the treatment of patients with moderate-to-severe genital psoriasis. It is being investigated in a phase 2 study for treatment of palmoplantar pustulosis.

In February 2021, we announced the submission of an sNDA to the FDA for the treatment of adults with mild-to-moderate plaque psoriasis who are candidates for phototherapy or systemic therapy.

In May 2021, we announced that the FDA had accepted for review our sNDA for the treatment of adults with mild-to-moderate plaque psoriasis who are candidates for phototherapy or systemic therapy. The FDA had set a PDUFA action date of December 19, 2021.

In December 2021, we announced that the FDA had approved the expanded indication for Otezla for the treatment of adult patients with plaque psoriasis, who are candidates for phototherapy or systemic therapy, across all severities.

Repatha

Repatha is a human monoclonal antibody that inhibits PCSK9. It is being investigated as a treatment for atherosclerotic CV disease in high-risk patients with high LDL-C without prior heart attack or stroke.

Rozibafusp alfa

Rozibafusp alfa is a novel antibody-peptide conjugate that simultaneously blocks the BAFF and ICOSL activity. It is being investigated as a treatment for systemic lupus erythematosus.

Tarlatamab

Tarlatamab is an HLE anti- DLL3 x anti-CD3 BiTE® molecule. It is being investigated for the treatment of small cell lung cancer.

TEZSPIRE

TEZSPIRE is a human monoclonal antibody that inhibits the action of thymic stromal lymphopoietin. It is being evaluated in phase 3 studies as a treatment for severe asthma and chronic rhinosinusitis with nasal polyps. It is also being investigated in phase 2 studies as a treatment for chronic obstructive pulmonary disease and chronic spontaneous urticaria. TEZSPIRE is being developed jointly in collaboration with AstraZeneca.

In May 2021, we announced that our partner AstraZeneca had submitted a BLA to the FDA for tezepelumab, a potential first-in-class medicine in severe asthma.

In July 2021, we announced that the FDA had accepted a BLA and granted Priority Review of TEZSPIRE for the treatment of asthma.

In December 2021, we announced that the FDA had approved Amgen and AstraZeneca's TEZSPIRE for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

In January 2022, we announced that TEZSPIRE is available for shipment to wholesalers in the United States.

AMG 451/KHK4083

AMG 451/KHK4083 is a monoclonal antibody that inhibits OX-40. It is being investigated for the treatment of moderate-to-severe atopic dermatitis. AMG 451/KHK4083 is being developed in collaboration with KKC.

ABP 654

ABP 654, a biosimilar candidate to STELARA (ustekinumab), is a monoclonal antibody that inhibits IL-12 and IL-23. It is being investigated in a phase 3 study for biosimilarity to STELARA. The reference-product primary conditions are psoriasis, psoriatic arthritis and Crohn’s disease.

ABP 938

ABP 938, a biosimilar candidate to EYLEA, is a VEGFR Fc fusion protein. It is being investigated in a phase 3 study for biosimilarity to EYLEA. The reference-product primary conditions are wet AMD, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy.

ABP 959

ABP 959, a biosimilar candidate to SOLIRIS, is a monoclonal antibody that specifically binds to the complement protein C5. It is being investigated in a phase 3 study for biosimilarity to SOLIRIS. The reference-product primary conditions are PNH and aHUS.

Business Relationships

From time to time, we enter into business relationships, including joint ventures and collaborative arrangements, for the R&D, manufacture and/or commercialization of products and/or product candidates. In addition, we acquire product and R&D technology rights and establish R&D collaborations with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed-product base. These arrangements generally provide for nonrefundable, upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. The activities under these collaboration agreements are performed with no guarantee of either technological or commercial success, and each is unique in nature.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require counterparties to execute confidentiality agreements upon commencement of a business relationship with us. However, others could either develop independently the same or similar information or unlawfully obtain access to our information.

BeiGene, Ltd.

On January 2, 2020, we acquired a 20.5% stake in BeiGene for approximately $2.8 billion in cash as part of a collaboration to expand our oncology presence in China. Under the collaboration, BeiGene began selling XGEVA in 2020, BLINCYTO in 2021 and KYPROLIS in early 2022 in China, and Amgen shares profits and losses equally during the initial product-specific commercialization periods; thereafter, product rights may revert to Amgen, and Amgen will pay royalties to BeiGene on sales in China of such products for a specified period.

In addition, we jointly develop a portion of our oncology portfolio with BeiGene, which shares in global R&D costs by providing cash and development services of up to $1.25 billion. Upon regulatory approval, BeiGene will assume commercialization rights in China for a specified period, and Amgen and BeiGene will share profits equally until certain of these product rights revert to Amgen. Upon return of the product rights, Amgen will pay royalties to BeiGene on sales in China for a specified period. For product sales outside China, Amgen will also pay royalties to BeiGene.

Novartis

We are in a collaboration with Novartis to jointly develop and commercialize Aimovig. On January 31, 2022, concurrent with the settlement of the previously disclosed litigation between Amgen and Novartis we modified the terms of the collaboration. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Arrangement through December 31, 2021

In the United States, Amgen and Novartis jointly developed and collaborated on the commercialization of Aimovig. Amgen, as the principal, recognized product sales of Aimovig in the United States, shared U.S. commercialization costs with Novartis and paid Novartis a significant royalty on net sales in the United States. Novartis held global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig (the ex-U.S. Novartis Rights). Novartis paid Amgen double-digit royalties on net sales of the product in the ex-U.S. Novartis Rights territories and funded a portion of global R&D expenses. In addition, Novartis was required to make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds were achieved with respect to Aimovig in the United States.

Arrangement after January 1, 2022

Pursuant to the amendment effective January 1, 2022, Novartis retains the ex-U.S. Novartis Rights and will continue to pay double-digit royalties on net sales in the ex-U.S. Novartis Rights territories. In the United States, Novartis will no longer collaborate with Amgen, share Aimovig commercialization costs or pay milestones and Amgen will no longer pay royalties to Novartis on sales of Aimovig. Amgen and Novartis will continue to share development expenses worldwide.

Amgen manufactures and supplies Aimovig worldwide.

DaVita Inc.

In January 2017, we entered into a six-year supply agreement with DaVita, which superseded the previously existing, seven-year supply agreement that commenced in 2012. Pursuant to the 2017 agreement, we supply EPOGEN and Aranesp in amounts necessary to meet specified annual percentages of DaVita's and its affiliates' requirements for ESAs used in providing dialysis services in the United States and Puerto Rico. Such percentages vary during the term of the agreement, but in each year are at least 90%. The agreement expires in December 2022. The agreement may be terminated by either party before expiration of its term in the event of certain breaches of the agreement by the other party.

For financial information about our significant collaborative arrangements, see Part IV—Note 8, Collaborations, to the Consolidated Financial Statements.

Human Capital Resources

Overview

Amgen's approach to human capital resource management starts with our mission to serve patients. We strive to serve patients by transforming the promise of science and biotechnology into therapies that have the power to restore health or save lives. The way we approach our business is guided by our Amgen Values:

Amgen Values			
Be Science-Based	Compete Intensely and Win	Create Value for Patients, Staff and Stockholders	Be Ethical
Trust and Respect Each Other	Ensure Quality	Work in Teams	Collaborate, Communicate and Be Accountable

Our staff are also guided by the Company's Code of Conduct, which is designed to help every person who does business on our behalf worldwide (including all staff, management, consultants, contract workers and temporary workers) to understand what is expected of them.

Our industry exists in a complex regulatory and reimbursement environment. The unique demands of our industry, together with the challenges of running an enterprise focused on the discovery, development, manufacture and commercialization of innovative medicines, requires a highly engaged and committed workforce.

As of December 31, 2021, Amgen had approximately 24,200 staff members in over 50 countries, and we have had relatively low global turnover rates. We also supplement our workforce with independent contractors, contingent workers and temporary workers, as needed. Outside of the United States, some of our employees are represented by unions or works councils. We consider our staff relations to be good, supported by regular assessments of staff engagement surveys on a wide range of topics (including engagement in the COVID-19 environment, diversity, inclusion and belonging, and maintaining a culture of compliance). We discuss the results of these surveys with our workforce and our Board of Directors.

Compensation, Benefits and Development

Our approach to employee compensation and benefits is designed to deliver cash, equity and benefit programs that are competitive with those offered by leading companies in the biotechnology and pharmaceutical industries to attract, motivate and retain talent with a focus on encouraging performance, promoting accountability and adherence to Company values and alignment with the interests of the Company's shareholders.

Our base pay program aims to compensate staff members relative to the value of the contributions of their role, which takes into account the skills, knowledge and abilities required to perform each position, as well as the experience brought to the job. We also provide annual incentive programs to reward our staff in alignment with achievement of Company-wide goals that are established annually and designed to drive aspects of our strategic priorities that support and advance our strategy across our Company. The majority of our staff members are also eligible for the grant of equity awards under our long-term incentive program that are designed to align the experience of these staff with that of our shareholders.

All staff also participate in a regular performance measurement process through which staff receive performance and development feedback, and pay is aligned to performance.

To support the development of our staff, we provide a variety of programs, including leadership development programs, virtual instructor-led courses and self-paced learning options.

Our benefit programs are also generally broad-based, promote health and overall well-being and emphasize saving for retirement. All regular U.S. staff members are eligible to participate in the same core health and welfare and retirement savings plans. Other U.S. employee benefits include medical plans, dental plans, adoption assistance, paid parental leave programs, access to childcare, employee assistance programs, employee stock purchase plan, flexible spending accounts, life, long-term care and business travel accident insurance, short and long-term disability benefits, wellness benefits and work-life resources and referrals. Comparable programs and benefits are available globally, with the same health and well-being intent, consistent with statutory requirements.

Our Compensation and Management Development Committee provides oversight of our compensation plans, policies and programs.

Safety and Wellness and Our Response to COVID-19

Creating a safe and healthy workplace for our staff is a priority at Amgen. Our goal is to have a world class safety record through safety leadership, risk management practices and integrating safety throughout our business processes. To foster our safety culture, we implement a comprehensive safety program, driving to understand and mitigate the root cause of safety incidents and manage and control variability. We use leading indicators to assess the effectiveness of our safety programs and make course corrections as needed. Additionally, we perform formal executive management review of functional safety performance for Operations, Global Commercial Operations and R&D on a quarterly basis with a focus on identifying early signals and taking action to drive continuous improvement.

In response to the COVID-19 pandemic and as part of our commitment to work to ensure the safety and well-being of our employees, for 2020 and much of 2021, we have activated our applicable business continuity plans, including having those of our employees who were able to work from home to do so, and for employees returning to the workplace and the field, we took additional safety measures, including implementing occupancy limits, restricting business travel, providing and requiring the use of personal protective equipment, temperature screening and COVID-19 testing to access our workplaces. Staff member access to our facilities has been in accordance with applicable government health and safety protocols and guidance issued in response to the COVID-19 pandemic, and in 2021 we required staff members in the United States and Puerto Rico to be fully vaccinated against COVID-19.[1] In the fourth quarter of 2021, we enabled our U.S. based workforce to return to the workplace for work that benefits from face-to-face interactions, while maintaining appropriate safety measures to ensure staff well-being. This approach intentionally combines the benefits of remote and in-person working at Amgen for the future as COVID-19 restrictions ease around the globe. We will continue to learn and adapt this approach as needed for the future.

Our Corporate Responsibility and Compliance Committee provides general oversight of our safety programs and initiatives, while our Board of Directors, as a whole, has overseen our specific responses to the COVID-19 pandemic.

Diversity, Inclusion and Belonging

We believe that a diverse and inclusive culture fosters innovation, which supports our ability to serve patients. Further, we also believe our global presence is strengthened by having a workforce that reflects the diversity of the patients we serve. It is with these beliefs in mind that we have continued to strengthen and grow our culture of diversity, inclusion and belonging. Our internal efforts include, in 2019, establishing a Diversity, Inclusion and Belonging Council chaired by our Chief Executive Officer. In 2020, we implemented a global unconscious-bias training program, and we launched an ongoing learning journey with tools and resources that guides staff on the role they play in creating diversity, inclusion and belonging throughout the organization. Each of Amgen's ERGs is sponsored by an executive leader who reports to the CEO. We are leveraging our ERGs to represent and support the diversity of Amgen staff, while also providing opportunities to Amgen's business and the community.

[1] The vaccination requirement did not apply to staff who were unable to receive a COVID-19 vaccine because of qualifying religious or medical reasons.

Employee Resource Groups	
Amgen Asian Association (AAA)	Amgen Black Employee Network (ABEN)
Ability Bettered through Leadership and Education (ABLE), a resource group for those with disabilities, visible and invisible, including those conditions also experienced by the patients that Amgen serves.	
Amgen Early Career Professionals (AECP)	Amgen Indian Subcontinent Network (AISN)
Amgen Latin Employee Network (ALEN)	Amgen LGBTQ and Allies Network (PRIDE)
Amgen Veterans Employees Network (AVEN)	Women Empowered to be Exceptional (WE2)
Women in Information Systems Enrichment (WISE)	Amgen International Network (AIN)

For 2021, to tangibly deepen and drive our diversity, inclusion and belonging activities enterprise-wide and actively communicate our culture of belonging to all staff, we established an annual diversity, inclusion and belonging goal for leaders at executive director and above levels to establish, document and execute diversity, inclusion and belonging action plans, with a target goal of 75% participation, which we achieved and exceeded in 2021.

In areas of underrepresentation, we develop plans with a goal of bringing our representation in line with availability. We engage in outreach efforts to attract, retain and advance more women and minorities in our workforce. For example, we have worked to enhance our diverse candidate recruiting pool by developing relationships with organizations that can serve as a source of diverse candidates, such as the National Black MBA Association and National Sales Network, as well as historically black colleges and universities. In 2021, a fellowship program between Amgen and Howard University was established to expand the talent pool and diversify ranks in research and development.

Additionally, at the end of 2020, we became a founding member of OneTen, a coalition of the world's largest, best-known companies, that aims to hire one million Black Americans (with a specific focus on those without four-year college degrees) into good-paying, family-sustaining jobs over the next ten years. As a member of OneTen, Amgen is taking a leadership role in the greater Los Angeles region, where the company is headquartered, to help expand the coalition organizations that share our desire to offer opportunities to diverse talent. Other examples of actions that we are taking in this area include investment and participation in the Healthcare Businesswomen's Association (a global organization focused on development and business networking for women in healthcare) and the UCLA Anderson School of Management leadership programs for women and underrepresented talent.

Our 2020 Consolidated EEO-1 Report can be viewed on our website at www.amgen.com (the website address is not intended to function as a hyperlink, and the information contained in our website is not intended to be a part of this filing).

In 2021, our Corporate Responsibility and Compliance Committee provided oversight of our policies, programs and initiatives focusing on workforce diversity and inclusion. In 2022, oversight of diversity, inclusion and belonging shifted to the Compensation and Management Development Committee, which also provides oversight of our human capital management.

Information about Our Executive Officers

The executive officers of the Company as of February 16, 2022, are set forth below.

Mr. Robert A. Bradway, age 59, has served as a director of the Company since 2011 and Chairman of the Board of Directors since 2013. Mr. Bradway has been the Company's President since 2010 and Chief Executive Officer since 2012. From 2010 to 2012, Mr. Bradway served as the Company's President and Chief Operating Officer. Mr. Bradway joined the Company in 2006 as Vice President, Operations Strategy, and served as Executive Vice President and Chief Financial Officer from 2007 to 2010. Prior to joining the Company, Mr. Bradway was a Managing Director at Morgan Stanley in London, where, beginning in 2001, he had responsibility for the firm's banking department and corporate finance activities in Europe. Mr. Bradway has been a director of The Boeing Company, an aerospace company and manufacturer of commercial airplanes, defense, space and securities systems, since 2016. He has served on the board of trustees of the University of Southern California since 2014. From 2011 to 2017, Mr. Bradway was a director of Norfolk Southern Corporation, a transportation company.

Mr. Murdo Gordon, age 55, became Executive Vice President, Global Commercial Operations, in 2018. Prior to joining the Company, Mr. Gordon was Chief Commercial Officer at BMS, a pharmaceutical company, from 2016 to 2018. Mr. Gordon served as Head of Worldwide Markets at BMS from 2015 to 2016. Prior to this, Mr. Gordon served in a variety of leadership roles at BMS for more than 25 years.

Mr. Jonathan P. Graham, age 61, became Executive Vice President, General Counsel and Secretary in 2019. Mr. Graham joined the Company in 2015. From 2015 to 2019, Mr. Graham was Senior Vice President, General Counsel and Secretary. Prior to joining Amgen, from 2006 to 2015, Mr. Graham was Senior Vice President and General Counsel at Danaher Corporation. From 2004 to 2006, Mr. Graham was Vice President, Litigation and Legal Policy, at General Electric Company (GE). Prior to GE, Mr. Graham was a partner at Williams & Connolly LLP.

Mr. Peter H. Griffith, age 63, became Executive Vice President and Chief Financial Officer in 2020. Mr. Griffith joined the Company in 2019 as Executive Vice President, Finance. Prior to joining Amgen, Mr. Griffith was President of Sherwood Canyon Group, LLC, a private equity firm. From 1997 to 2019, Mr. Griffith was a partner at EY, an accounting and professional services firm, and served in a variety of senior leadership roles, with his last position being Global Vice Chair, Corporate Development. Prior to EY, Mr. Griffith was a Managing Director and head of the investment banking division of Wedbush Securities Inc.

Ms. Nancy A. Grygiel, age 54, became Senior Vice President and Chief Compliance Officer in 2020. Ms. Grygiel joined the Company in 2015. From 2016 to 2020, Ms. Grygiel was Vice President, Compliance. Prior to joining Amgen, from 2011 to 2015, Ms. Grygiel served as Vice President, Compliance, Corporate & International, at Allergan, Inc. (Allergan). Prior to Allergan, Ms. Grygiel held several management positions at Mylan Pharmaceuticals, Inc.

Ms. Lori A. Johnston, age 57, became Executive Vice President, Human Resources, in 2019. From 2016 to 2019, Ms. Johnston served as the Company's Senior Vice President, Human Resources. From 2012 to 2016, Ms. Johnston was Executive Vice President and Chief Administrative Officer of Celanese Corporation (Celanese). Prior to Celanese, Ms. Johnston served in a series of progressive leadership roles at Amgen from 2001 to 2012, with her last position being Vice President, Human Resources. Prior to joining the Company, Ms. Johnston held human resources and other positions at Dell Inc.

Ms. Rachna Khosla, age 49, became Senior Vice President, Business Development, in 2021. Ms. Khosla joined the Company in 2013 as Corporate Development Director. From 2016 to 2018, Ms. Khosla was Executive Director, Business Development, and from 2018 to 2021, was Vice President, Business Development. Prior to joining the Company, Ms. Khosla was a Director at Lazard Ltd. (Lazard) responsible for healthcare mergers and acquisitions. Prior to Lazard, Ms. Khosla had various roles at Credit Suisse Group AG, Sanofi Aventis, Aventis Capital, J.P. Morgan Chase & Co., and Salomon Brothers, Inc.

Dr. David M. Reese, age 59, became Executive Vice President, R&D, in 2018. Dr. Reese joined the Company in 2005 and has held leadership roles in development, medical sciences and discovery research. Dr. Reese was Senior Vice President, Translational Sciences and Oncology, from 2017 to 2018 and Senior Vice President, Translational Sciences, from 2015 to 2017. Prior to joining Amgen, Dr. Reese was director of Clinical Research at the Breast Cancer International Research Group from 2001 to 2003 and a cofounder, president and chief medical officer of Translational Oncology Research International, a not-for-profit academic clinical research organization, from 2003 to 2005. Dr. Reese previously served on the faculty at UCLA and the University of California, San Francisco.

Mr. Esteban Santos, age 54, became Executive Vice President, Operations, in 2016. Mr. Santos joined the Company in 2007 as Executive Director, Manufacturing Technologies. From 2008 to 2013, Mr. Santos held a number of Vice President roles at the Company in engineering, manufacturing, site operations and drug product. From 2013 to 2016, Mr. Santos was Senior Vice President, Manufacturing. Prior to joining the Company, Mr. Santos served as Site General Manager of J&J's Cordis operation in Puerto Rico. Prior to J&J, Mr. Santos held several management positions in GE's industrial and transportation businesses.

Geographic Area Financial Information

For financial information concerning the geographic areas in which we operate, see Part IV—Note 3, Revenues and Note 11, Property, plant and equipment, to the Consolidated Financial Statements.

Investor Information

Financial and other information about us is available on our website at www.amgen.com. We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with or furnish it to the U.S. Securities and Exchange Commission (SEC). In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected without charge at the SEC's website at www.sec.gov. (These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.)

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

SUMMARY

Risks Related to Economic Conditions and Operating a Global Business, Including During the COVID-19 Pandemic

- The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, manufacturing, supply chains, distribution systems, product development, product sales, business and results of operations.
- A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.
- Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.

Risks Related to Government Regulations and Third-Party Policies

- Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.
- Guidelines and recommendations published by various organizations can reduce the use of our products.
- The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability.
- Our business may be affected by litigation and government investigations.

Risks Related to Competition

- Our products face substantial competition and our product candidates are also likely to face substantial competition.
- Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.
- We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.

- Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively affect our business.

Risks Related to Research and Development

- We may not be able to develop commercial products despite significant investments in R&D.
- We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.
- Our current products and products in development cannot be sold without regulatory approval.
- Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.
- Some of our pharmaceutical pipeline and our commercial product sales rely on collaborations with third parties, which may adversely affect the development and sale of our products.
- Our efforts to collaborate with or acquire other companies, products, or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.

Risks Related to Operations

- We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.
- We rely on third-party suppliers for certain of our raw materials, medical devices and components.
- Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.
- Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives.
- The effects of global climate change and related natural disasters could negatively affect our business and operations.

General Risk Factors

- Global economic conditions may negatively affect us and may magnify certain risks that affect our business.
- Our stock price is volatile.
- We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

RISKS RELATED TO ECONOMIC CONDITIONS AND OPERATING A GLOBAL BUSINESS, INCLUDING DURING THE COVID-19 PANDEMIC

The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, manufacturing, supply chains, distribution systems, product development, product sales, business and results of operations.

The novel coronavirus identified in late 2019, SARS-CoV-2, which causes the disease known as COVID-19, is an ongoing global pandemic that has resulted in public and governmental efforts to contain or slow the spread of the disease, including widespread shelter-in-place orders, social distancing interventions, quarantines, travel restrictions and various forms of operational shutdowns. The COVID-19 pandemic and the resulting measures implemented in response to the pandemic are adversely affecting, and are expected to continue to adversely affect, our business (including our R&D, clinical trials, operations, manufacturing, supply chains, distribution systems, product development and sales activities), the business activities of our suppliers, customers, third-party payers and our patients. See *Our current products and products in development cannot be sold without regulatory approval*; see also *We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications*. Due to the pandemic and these measures and their effects, we have experienced, and

expect to continue to experience, unpredictable reductions in demand for certain of our products, exacerbated by COVID-19 surges resulting in repeated shutdowns and/or disruptions in certain geographies.

Federal, state and local, and international governmental policies and initiatives designed to reduce the transmission of COVID-19 also have resulted in the cancellation or delay of diagnostic, elective, specialty and other procedures and

appointments to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19. For example, an NPR/Harvard poll in 2021 found that, with hospitals crowded from COVID-19, one in five U.S. households has had to delay care for serious illnesses. These measures and challenges will likely continue to varying degrees for the duration of the pandemic and have significantly reduced patient access to, and administration of, certain of our drugs. For example, Prolia requires administration by a healthcare provider in doctors' offices or other healthcare settings that are affected by COVID-19. The U.S. label for Prolia instructs healthcare professionals who discontinue Prolia to transition the patient to an alternative antiresorptive, including oral treatments that do not require administration by a healthcare provider. Further, as a result of COVID-19, oncology patients, in consultation with their doctors, may be selecting therapies that are less immunosuppressive or therapies that do not require administration in a hospital setting, potentially adversely affecting sales of certain of our products. Also, new patients have been, and are expected to continue to be, less likely to be diagnosed and/or to start therapeutics during the pandemic, and these effects, together with the lower treatment rates during the pandemic, have had, and are expected to continue to have, a cumulative negative effect on the commercial performance of our business. The decrease in diagnoses over the course of the pandemic has suppressed the volume of new patients starting treatment, which we expect to continue to impact our business. Once the pandemic subsides, we anticipate there could be a backlog of patients seeking appointments with physicians relating to a variety of medical conditions, and as a result, patients seeking treatment with certain of our products may have to navigate lower provider capacity, and this lower provider capacity could have a continued adverse effect on our sales following the opening up of various geographies and/or the end of the pandemic. Further, the effects of the COVID-19 pandemic may result in long-term shifts in preferences among healthcare professionals and patients toward treatments that do not require administration by healthcare professionals or visits to medical facilities.

As the pandemic continues, and if conditions worsen or if the duration of the pandemic extends significantly, we expect to experience additional adverse effects on our development, operational and commercial activities, customer purchases and our collections of accounts receivable. It remains uncertain the degree to which these adverse effects would impact our future operational and commercial activities, customer purchases and our collections as conditions begin to improve. There was a resurgence in COVID-19 infections in numerous jurisdictions in 2021, resulting in the reinstatement of stricter restrictions and shutdowns in a number of jurisdictions, including in the United States, Europe and Asia Pacific regions. It is expected that the pandemic will continue to ebb and flow, with different jurisdictions having higher levels of infections than others over the course of the pandemic. New variants of the SARS-CoV-2 virus have emerged, including the delta and omicron variants, and have been shown to be present in many geographies and appear to spread more easily and quickly than other variants. Further, although some studies suggest that antibodies generated with currently authorized vaccines may be effective against these variants, it remains uncertain whether currently available vaccines will retain their efficacy against future variants of the virus. Further, even while vaccine booster shots are available for certain patients, persistent vaccine hesitancy may result in under-vaccinated populations which may prolong the duration of the COVID-19 pandemic and continue to disrupt the availability of healthcare services to the patients we serve. Jurisdictions may implement, continue or reinstate border closures, impose or reimpose prolonged quarantines and further restrict travel and business activity. These measures could significantly affect our ability to support our operations and customers and the ability of our employees to get to their workplaces to discover, study, develop and produce our product candidates and products, disrupt the movement of our products through the supply chain, and further prevent or discourage patients from participating in our clinical trials, seeking healthcare services and the administration of certain of our products. The increased availability of remote working arrangements in response to the COVID-19 pandemic has expanded the pool of companies that can compete for our employees and employment candidates. Further, in connection with the global outbreak and spread of COVID-19 and in an effort to increase the wider availability of needed medical products, we or our suppliers may elect to, or governments may require us or our suppliers to, allocate manufacturing capacity (for example pursuant to the U.S. Defense Production Act) in a way that adversely affects our regular operations, customer relationships and financial results. In the United States, on January 21, 2021, President Biden issued an Executive Order instructing federal agencies to use all available legal authorities, including the Defense Production Act, to improve current and future pandemic response and biological threat preparedness. The rapid reallocation of resources for the treatment and prevention of COVID-19 (including the production of COVID-19 vaccinations or related therapies, such as our agreement to contribute to the production of COVID-19 antibody therapies for Lilly) and/or disruptions and shortages in the global supply chain caused by the pandemic, could also result in increased competition for, or reduced availability of, materials or components used in the development, manufacturing, distribution, or administration of our products. For example, during the second quarter of 2021, an industry-wide shortage of certain lab kit supplies necessary for some activities that support our clinical

trials has developed that we are actively monitoring and managing. We have also experienced challenges in obtaining certain COVID-19-related supplies, including COVID-19 antigen rapid test kits for our staff, as a result of high demand and limited supplies during the omicron variant surge. In addition, unpredictable increases in demand for certain of our products could exceed our capacity to meet such demand, which could adversely affect our financial results and customer relationships.

The COVID-19 pandemic and the volatile global economic conditions stemming from it may precipitate or amplify the other risks described in this “Risk Factors” section, which could materially adversely affect our business, operations and

financial condition and results. For example, if a natural disaster or other potentially disruptive event occurs concurrently with the COVID-19 pandemic, such disaster or event could deplete our inventory levels and we could experience a disruption to our manufacturing or ability to supply our products.

The rapid development and fluidity of the pandemic precludes any prediction as to the ultimate effect of COVID-19 on us. The duration of the measures being taken by the authorities to mitigate against the spread of COVID-19 (including the distribution and/or availability of vaccines and boosters), and the extent to which such measures are effective, if at all, remain highly uncertain. The magnitude and degree of COVID-19's adverse effect on our business (including our product development, product sales, operating results and resulting cash flows) and financial condition will be driven by the severity and duration of the pandemic, the pandemic's effect on the United States and global economies and the timing, scope and effectiveness of federal, state, local and international governmental responses to the pandemic. If mitigation of the pandemic continues to require further shelter-in-place and shutdown orders and/or restrictions on individual and/or group conduct, any adverse effects of the COVID-19 pandemic will likely grow and could be enduring, and our business and financial position could be materially adversely affected.

A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.

To achieve our business objectives, we rely on sophisticated information technology systems, including software, mobile applications, cloud services and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or adversely affect our reputation.

Our information technology systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. Further, as the majority of our employees are working remotely, our reliance on our and third-party information technology systems has increased substantially and is expected to continue to increase. The complexity and interconnected nature of our systems makes them potentially vulnerable to breakdown or other service interruptions. Upgrades or changes to our systems or the software that we use may result in the introduction of new cybersecurity vulnerabilities and risks. Our systems are also subject to frequent cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Such attacks could include the use of harmful and virulent malware, including ransomware or other denials of service, that can be deployed through various means, including the software supply chain, e-mail, malicious websites and/or the use of social engineering. We have also experienced denial of service attacks against our network, and although such attacks did not succeed, there can be no assurance that our efforts to guard against the wide and growing variety of potential attack techniques will be successful in the future. Attacks such as those experienced by governmental entities (including those that approve and/or regulate our products, such as the EMA) and other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access or protect important data, and could have a material adverse effect on our ability to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and/or distributing our products. For example, in 2017, a pharmaceutical company experienced a cyberattack involving virulent malware that significantly disrupted its operations, including its research and sales operations and the production of some of its medicines and vaccines. As a result of the cyberattack, its orders and sales for certain products in certain markets were negatively affected. In December 2020, SolarWinds Corporation, a leading provider of software for monitoring and managing information technology infrastructure, disclosed that it had suffered a cybersecurity incident whereby attackers had inserted malicious code into legitimate software updates for its products that were installed by myriad private and government customers, enabling the attackers to access a backdoor to such systems.

Our systems also contain and utilize a high volume of sensitive data, including intellectual property, trade secrets, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials and/or personal information belonging to us, our staff, our patients, customers and/or other parties. In some cases, we utilize third-party service providers to process, store, manage or transmit such data, which may increase our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) resulting from attacks or lapses by employees, service providers (including providers of information technology-specific services), nation states (including groups associated with or supported by foreign intelligence agencies), organized crime organizations,

“hacktivists” or others, create risks that our sensitive data may be exposed to unauthorized persons, our competitors, or the public. For example, a supplier recently experienced a data breach in which an unauthorized third party acquired access to certain information provided to the supplier in the course of its provision of services to us, including business documents and certain personally identifiable patient information (not including social security or other financial or health insurance information). As required, we promptly notified the applicable state attorneys general and the individuals whose personally identifiable information was affected of this data breach at the supplier. Although the supplier data breach did not result in a material adverse effect on our business, there can be no assurance that a similar

future cybersecurity incident would not result in a material adverse effect on our business or results of operations. Another vendor experienced a cyberattack and, while initially reporting that our information was not involved, the vendor subsequently informed us that the attacker had accessed limited, non-significant information. Although this breach did not have a significant adverse effect on us, we may not receive timely reporting of future breaches. Cyberattackers are increasingly exploiting vulnerabilities in commercially available software from shared or open-source code. We rely on third party commercial software that may have such vulnerabilities, but as use of open-source code is frequently not disclosed, our ability to fully assess this risk to our systems is limited. For example, in December 2021, a remote code execution vulnerability was discovered in a widely used software library that is used in a variety of commercially available software and services. Although this vulnerability has not resulted in any significant adverse effects on us, there can be no assurances that a similar future vulnerability in the software and services that we use would not result in a material adverse effect on our business or results of operations.

Domestic and global government regulators, our business partners, suppliers with whom we do business, companies that provide us or our partners with business services, and companies we have or may acquire face similar risks, and security breaches of their systems or service outages could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data or sensitive personal information. For example, in 2019, two vendors that perform testing and analytical services that we use in developing and manufacturing our products experienced cyberattacks, and in April and September of 2020, vendors that provide us with information technology services and clinical data services, respectively, each experienced ransomware attacks. Although there was no breach of our systems, each of these incidents required us to disconnect our systems from those vendors' systems. While we were able to reconnect our systems following restoration of these vendors' capabilities without significantly affecting product availability, a more extended service outage affecting these or other vendors, particularly where such vendor is the single source from which we obtain the services, could have a material adverse effect on our business or results of operations. In addition, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers and patients.

Although we have experienced system breakdowns, attacks and information security breaches, we do not believe such breakdowns, attacks and breaches have had a material adverse effect on our business or results of operations. We continue to invest in the monitoring, protection and resilience of our critical and/or sensitive data and systems. However, there can be no assurances that our efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks and/or breaches of our systems that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in material financial, legal, business or reputational harm to us or negatively affect our stock price. While we maintain cyber-liability insurance, our insurance is not sufficient to cover us against all losses that could potentially result from a service interruption, breach of our systems or loss of our critical or sensitive data.

We are also subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and developing and the subject of significant attention globally. For example, we are subject to the European Union's General Data Protection Regulation, which became effective in May 2018, and the California Consumer Privacy Act of 2018 (CCPA), which became effective in January 2020, both of which provide for substantial penalties for non-compliance. The CCPA was amended in late 2020, to create the California Privacy Rights Act to create opt-in requirements for the use of sensitive personal data and the formation of a new dedicated agency for the enforcement of the law, the California Privacy Protection Agency. Since then, Virginia and Colorado both passed similar consumer privacy laws that will go into effect in 2023. Other jurisdictions where we operate have passed, or continue to propose, similar legislation and/or regulations. Failure to comply with these current and future laws could result in significant penalties and reputational harm and could have a material adverse effect on our business and results of operations.

Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.

As we continue our expansion efforts in emerging markets around the world, through acquisitions and licensing transactions as well as through the development and introduction, both independently and through collaborations

such as our collaboration with BeiGene, of our products in new markets, we face numerous risks to our business. There is no guarantee that our efforts and strategies to expand sales in emerging markets will succeed. Our international business, including in China and emerging market countries, may be especially vulnerable to periods of global and local political, legal, regulatory and financial instability, including issues of geopolitical relations, the imposition of international sanctions in response to certain state actions and/or sovereign debt issues. If relations between the United States and other governments deteriorate, our business and investments such markets may also be adversely affected. We may also be required to increase our reliance on third-party agents and unfamiliar operations and arrangements including those previously utilized by companies we partner with or acquire

in emerging markets. See *We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications*. Our expansion efforts in China and emerging markets around the world is dependent upon the establishment of an environment that is predictable, navigable and supportive of biopharmaceutical innovation, sustained access for our products and predictable pricing controls. For example, China continues to strengthen regulations on the collection, use and transmission of Chinese human genetic resources, and has expanded regulations on the conduct of biotechnology R&D activities in China. Our applications to the HGRAC seeking approval to conduct clinical trials in China are delayed pending further guidance from HGRAC. Our international operations and business may also be subject to less protective intellectual property or other applicable laws, diverse data privacy and protection requirements, changing tax laws and tariffs, trade restrictions or other barriers designed to protect industry in the home country against foreign competition, far-reaching antibribery and anticorruption laws and regulations and/or evolving legal and regulatory environments.

As we expand internationally, we are subject to fluctuations in foreign currency exchange rates relative to the U.S. dollar. While we have a program in place that is designed to reduce our exposure to foreign currency exchange rate fluctuations through foreign currency hedging arrangements, our hedging efforts do not completely offset the effect of these fluctuations on our revenues and earnings. In addition, we have a number of financial instruments referencing the LIBOR. On July 27, 2017, the U.K. Financial Conduct Authority, which regulates LIBOR, announced that it will no longer require banks to submit rates for the calculation of LIBOR to the LIBOR administrator after 2021, and it is anticipated that LIBOR will be completely phased out and replaced by 2023. In March 2020 and in January 2021, the FASB issued a new accounting standard to ease the financial burdens of the expected market transition from LIBOR and other interbank offered rates to alternative reference rates. While it appears likely that SOFR will be the replacement reference rate adopted in the market, the specific mechanisms to replace LIBOR in our existing LIBOR-linked financial instruments have not been finalized. As such, the replacement of LIBOR could have an adverse effect on the market for, or value of, our LIBOR-linked financial instruments. See Part IV—Note 1, Summary of significant accounting policies—Recent accounting pronouncements. We are also subject to the economic and political uncertainties stemming from the United Kingdom's exit from the EU, commonly referred to as "Brexit," which occurred on January 31, 2020. While our manufacturing and packaging activities take place largely outside the United Kingdom, minimizing the need to make costly and significant changes to those operations, we have nevertheless been working to put in place contingency plans to attempt to mitigate the effects of Brexit on us. Overall, the legal and operational challenges of our international business operations, along with government controls, the challenges of attracting and retaining qualified personnel and obtaining and/or maintaining necessary regulatory or pricing approvals of our products, may result in material adverse effects on our international product sales, business and results of operations.

RISKS RELATED TO GOVERNMENT REGULATIONS AND THIRD-PARTY POLICIES

Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.

Sales of our products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers continue to pursue initiatives to manage drug utilization and contain costs. These payers are increasingly focused on costs, which have resulted, and are expected to continue to result, in lower reimbursement rates for our products or narrower populations for whom payers will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payer dynamics, have limited, and are likely to continue to limit, our ability to set or adjust the price of our products based on their value, which can have a material adverse effect on our business. In the United States, particularly over the past few years, a number of legislative and regulatory proposals have been introduced in an attempt to lower drug prices. These include proposals that would allow the U.S. government to negotiate drug prices directly, limit drug reimbursement in Medicare and/or the commercial market based on reference prices or permit importation of drugs from Canada. Additional proposals would require a rebate to the government for any price increase in excess of the Consumer Price Index for All Urban Consumers and/or to shift some of the costs of these Medicare Part D reforms to manufacturers to offset the cost. Certain proposals focused on drug pricing have been adopted and additional proposals are likely to be adopted and implemented in some form.

—Changing U.S. federal coverage and reimbursement policies and practices have affected, and may continue to affect access to, pricing and sales of our products

A substantial portion of our U.S. business relies on reimbursement from federal government healthcare programs and commercial insurance plans regulated by federal and state governments. See Part I, Item 1. Business—Reimbursement. Our business has been and will continue to be affected by legislative actions changing U.S. federal reimbursement policy. Congress has been focused on drug pricing reforms and oversight since 2018, and this activity is still ongoing and has intensified. In 2019, 2020 and 2021, a number of Congressional committees debated drug pricing reform proposals and, in 2020, Amgen participated in House Oversight and Reform Committee hearings on drug pricing practices. In 2019, the Senate Finance Committee advanced a bill that would, among other things, penalize pharmaceutical manufacturers for raising prices on drugs

covered by Medicare Parts B and/or D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries and require higher/additional manufacturer discounts in Medicare Part D. Additionally, in late 2019, a drug-pricing bill, H.R. 3, passed the House of Representatives, which would, among other things, enable direct price negotiations by the federal government on certain drugs (with the maximum price paid by Medicare capped by prices derived from an international index), include a penalty for failing to reach agreement with the government and require that manufacturers offer these negotiated prices to other payers. In 2021, proposals from H.R. 3 were incorporated and adapted into other proposed legislation. These proposals, which included penalties if drug price benchmarks rise faster than inflation, Medicare price setting for certain drugs paid for under Parts B and D (whereby manufacturers must accept a price established by the government or face a penalty on all U.S. sales), and Part D redesign including a cap on beneficiary spending and a new manufacturer discount program, are also likely to be considered in a reconciliation bill that remains to be further debated between the Senate, House and White House. This framework remains in discussion with policymakers in Congress and the Administration. There are other outstanding proposals that, if enacted and implemented in whole or in part, could also affect access to and sales of our products, including, but not limited to, proposals to allow importation of prescription medications from Canada or other countries. In July 2021, the Administration issued an Executive Order designed to address anticompetitive behavior across multiple sectors, and for the healthcare sector, called for, among other things, the FDA to work with states and Indian Tribes to develop prescription drug importation programs, more scrutiny of anticompetitive activity by the FTC, emphasized the need for actions to allow for greater competition from generics and biosimilars, and included a process and timeline for federal agencies to deliver ideas to address drug pricing to the Administration. Subsequently, in September 2021, HHS released a report that presented guiding principles for the Administration's drug pricing proposals, including changes to promote competition throughout the prescription drug industry, highlighting potential legislative policies that Congress could pursue (including drug price negotiation in Medicare Parts B and D, making those negotiated prices available to commercial plans and legislation to speed the entry of biosimilar and generic drugs) and examples of potential administrative tools available to the HHS (including testing various models and enhanced focus of the FTC and the USPTO to address impediments to generic drug and biosimilar competition). Also, in response to the July 2021 Executive Order, the FDA sent a letter to the USPTO describing ways to strengthen coordination between the two agencies, offering training to help identify prior art, and seeking USPTO's views on practices that extend market exclusivities, whether pharmaceutical patent examiners need additional resources, and the effect of post-grant challenges at the PTAB on drug patents.

Legislation enacted in 2021 has also contained drug pricing reforms, including the Infrastructure Investment and Jobs Act and the American Rescue Plan Act of 2021 that include provisions requiring, starting in 2023, manufacturers to provide refunds to the government for discarded amounts of drugs from single use containers under Medicare Part B, and starting in 2024, increases the Medicaid rebate liability for certain medicines that raise prices in excess of inflation, respectively. The Infrastructure Investment and Jobs Act also delays implementation until January 1, 2026 of a final rule issued by HHS, that revises regulations under the federal antikickback statute to encourage PBMs to use rebates received from biopharmaceutical manufacturers to reduce patient cost-sharing at the point of sale under Medicare Part D. This rule is also subject to litigation, has numerous logistical hurdles to overcome before it can be effectively implemented, and it is unclear how PBMs will respond to the implementation of such rule. Further, a permanent repeal of this rule is also being considered in other legislation.

Our business has been, and is expected to continue to be, affected by changes in U.S. federal reimbursement policy resulting from federal regulations and federal demonstration projects. Over the past several years, federal agencies, including the CMS, announced a number of recommendations, policies, proposals and demonstration projects addressing drug pricing. The Administration has also developed and sought to advance a range of policy proposals that could impact U.S. federal reimbursement policy for drugs and biologics, including changes to Medicare Parts B and D. For example, in 2020, in response to an Executive Order, HHS released a rule to allow states to potentially enable the importation of certain drugs from Canada. While this rule is in litigation, should such litigation be unsuccessful, it could allow for the importation of Canadian versions of certain of Amgen's products (including Otezla), that could have a material adverse effect on Amgen's business. Also in response to an Executive Order, CMS released an interim final rule to implement the MFN pricing approach aimed at setting the reimbursement rate for 50 Medicare Part B drugs (including our products, such as Prolia, XGEVA, KYPROLIS, Neulasta, Nplate, EPOGEN and Aranesp) equal to the lowest adjusted price in 22 OECD nations for these drugs. In December 2021, subsequent to challenges, including procedural defects, CMS announced it was withdrawing the MFN rule. Notwithstanding the withdrawal of the rule, the MFN rule's approach to drug pricing and other similar approaches remain of interest to policymakers. In connection with its withdrawal of the MFN rule, CMS noted that it will "… explore all options to incorporate value into payments for Medicare Part B drugs, improve beneficiaries'

access to evidence-based care, and reduce drug spending for consumers and throughout the health care system." Further, we expect continued significant focus on healthcare and similar drug pricing proposals for the foreseeable future, including proposals under which the government would set drug prices or limit drug reimbursement.

CMS policy changes and demonstration projects to test new care, delivery and payment models can also significantly affect how drugs, including our products, are covered and reimbursed. For example, we believe that CMS' Oncology Care Model demonstration (which has since 2016 provided participating physician practices with performance-based financial

incentives that aim to manage or reduce Medicare costs without negatively affecting the efficacy of care) has reduced utilization of certain of our oncology products by participating physician practices and expect that it will continue to do so in the future. Further, HHS's September 2021 comprehensive plan to address drug pricing included potential future mandatory models that link payment for prescription drugs and biologics to factors such as: improved patient outcomes, reductions in health disparities, patient affordability and lower overall costs; bundled payment models; total cost of care models; models in which Medicare Part B savings from utilization of biosimilars, generics, or other high-value products are shared between prescribing providers and the government; additional Medicare Part D cost-sharing support for biosimilars and generics; and potential expansion of the Part D Senior Savings Model to additional classes of drugs. CMS also recently proposed a national coverage determination for Medicare which limits coverage of certain Alzheimer's disease medications approved by the FDA only to patients in qualifying clinical trials, suggesting that regulatory approval does not necessarily result in full Medicare coverage. In this dynamic environment, particularly in light of the pressures on healthcare budgets as a result of the pandemic, we are unable to predict which or how many federal policy, legislative, regulatory, executive or administrative changes may ultimately be, or effectively estimate the consequences to our business if, enacted and implemented. However, to the extent that these or other federal government initiatives further decrease or modify the coverage or reimbursement available for our products, require that we pay increased rebates or shift other costs to us, limit or affect our decisions regarding the pricing of or otherwise reduce the use of our U.S. products, or limit our ability to offer co-pay payment assistance to commercial patients, such actions could have a material adverse effect on our business and results of operations.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products. U.S. government price reporting regulations are complex and may require a biopharmaceutical manufacturer to update certain previously submitted data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data, we also may be required to pay additional rebates and provide additional discounts. CMS finalized a rule in December 2020 providing that, starting January 1, 2023, unless a manufacturer can ensure that the full amount of manufacturer patient assistance programs is passed on to the patient, such amount will be treated as a price reduction that will be taken into account when reporting our Best Price and/or Average Manufacturer Price. Given the use by PBMs and insurers of copay accumulator adjustment programs to apply such patient assistance for the benefit of such companies and not to defray costs to patients, it could be difficult to impossible for manufacturers to ensure that the full value of such amounts is being passed on to the patient. This new policy, if implemented, would have significant implications for our ability to offer copay assistance programs. Although implementation has been delayed by the current Administration, the prior Administration finalized a rule (which was to be effective January 1, 2022) mandating price and cost-sharing transparency for almost all health plans and insurers in the individual and group commercial markets. Additionally, the Administration recently finalized transparency provisions required under the Consolidated Appropriations Act of 2021 for health plans and insurer reporting of certain drug pricing information by December 27, 2022, and each June thereafter, resulting in a biennial public report highlighting drug pricing trends and the impact of prescription drug costs on premiums and out-of-pocket costs. It is unclear how group health plans and health insurers may respond.

—Changing reimbursement and pricing actions in various states have negatively affected, and may continue to negatively affect, access to, and have affected, and may continue to affect, sales of our products

At the state level, government actions or ballot initiatives can also affect how our products are covered and reimbursed and/or create additional pressure on our pricing decisions. A number of states have adopted, and many other states are considering, drug importation programs or other new pricing actions, including proposals designed to require biopharmaceutical manufacturers publicly to report proprietary pricing information, limit price increases or place a maximum price ceiling or cap on biopharmaceutical products. Existing and proposed state pricing laws have added complexity to the pricing of drugs and may already be affecting industry pricing decisions. For example, a California law, the constitutionality of which is currently being challenged, purports to require biopharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. Similar laws exist in Oregon and Washington. States are also seeking to change the way they pay for drugs for patients covered by state programs. California adopted a 2020-21 budget that incorporates international pricing into Medicaid supplemental rebate negotiations and allows its Medicaid program to seek federal approval to extend supplemental rebates to non-Medicaid populations. New York, Massachusetts and Ohio have established Medicaid drug spending caps, and additional states may consider doing so as they face budget deficits from the effects of COVID-19. Additionally, Colorado, Florida, Maine, New Hampshire, New Mexico and Vermont have enacted laws, and several other states have proposed laws, to facilitate the

importation of drugs from Canada. Other states could adopt similar approaches or could pursue different policy changes in a continuing effort to reduce their costs. Ultimately, as with U.S. federal government actions, existing or future state government actions or ballot initiatives may also have a material adverse effect on our product sales, business and results of operations.

—U.S. commercial payer actions have affected and may continue to affect access to and sales of our products

Payers, including healthcare insurers, PBMs, integrated healthcare delivery systems (vertically-integrated organizations built from the consolidation of healthcare insurers and PBMs) and group purchasing organizations, increasingly seek ways to reduce their costs. With increasing frequency, payers are adopting benefit plan changes that shift a greater proportion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient copay or coinsurance obligations and more significant limitations on patients' use of manufacturer commercial copay assistance programs. Further, government regulation of payers may affect these trends. For example, CMS finalized a policy in May 2020 (for plan years starting on or after January 1, 2021, and remains standing policy for 2022) that has caused commercial payers to more widely adopt copay accumulator adjustment programs. Payers have sought, and continue to seek, price discounts or rebates in connection with the placement of our products on their formularies or those they manage, particularly in treatment areas where the payer has taken the position that multiple branded products are therapeutically comparable. Payers also control costs by imposing restrictions on access to or usage of our products, such as Step Therapy, or requiring that patients receive the payer's prior authorization before covering the product or that patients use a mail-order pharmacy or a limited network of payer fully-owned mail-order or specialty pharmacies. Payers have also chosen to exclude certain indications for which our products are approved or chosen to exclude coverage entirely. For example, some payers require physicians to demonstrate or document that the patients for whom Repatha has been prescribed meet payer utilization management criteria, and these requirements have limited, and may continue to limit, patient access to Repatha treatment. In an effort to reduce barriers to access, we reduced the net price of Repatha by providing greater discounts and rebates to payers, including PBMs that administer Medicare Part D prescription drug plans. However, affordability of patient out-of-pocket co-pay cost has limited and may continue to limit patient use. For example, in late 2018 and early 2019, in response to a very high percentage of Medicare patients abandoning their Repatha prescriptions rather than pay their co-pay payment, we introduced a set of new National Drug Codes to make Repatha available at a lower list price to attempt to address affordability for patients, particularly those on Medicare, and on December 31, 2019, we discontinued the higher list price option for Repatha. Despite these net and list price reductions, some payers have restricted, and may continue to restrict, patient access and have and may continue to change formulary coverage for Repatha, seek further discounts or rebates or take other actions that could reduce our sales of Repatha. These factors have limited, and may continue to limit, patient affordability and use, and negatively affect Repatha sales.

Further, significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs, which places greater pressure on pricing and usage negotiations with biopharmaceutical manufacturers, significantly increasing discount and rebate requirements and limiting patient access and usage. For example, in the United States, as of the beginning of 2021, the top five integrated health plans and PBMs controlled about 85% of all pharmacy prescriptions. The consolidation among insurers, PBMs and other payers, including through integrated healthcare delivery systems and/or with specialty or mail-order pharmacies and pharmacy retailers, has increased the negotiating leverage such entities have over us and other biopharmaceutical manufacturers, and has resulted in greater price discounts, rebates and service fees realized by those payers. In 2019, 2020 and 2021, CVS, Express Scripts and United Health Group, respectively, each created Rebate Management Organizations that further increase their respective leverage to negotiate deeper discounts. Ultimately, additional discounts, rebates, fees, coverage or plan changes, restrictions or exclusions imposed by these commercial payers could have a material adverse effect on our product sales, business and results of operations. Policy reforms advanced by Congress or the Administration that refine the role of PBMs in the U.S. marketplace could have downstream implications or consequences for our business and how we interact with these entities. See *Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively affect our business.*

—Government and commercial payer actions outside the United States have affected and will continue to affect access to and sales of our products

Outside the United States, we expect countries will also continue to take actions to reduce their drug expenditures. See Part I, Item 1. Business—Reimbursement. IRP has been widely used by many countries outside the United States to control costs based on an external benchmark of a product's price in other countries. IRP policies can change quickly and frequently and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. Other expenditure control practices, including but not limited to the use of revenue clawbacks, rebates and percentage caps on price increases, are used in various

foreign jurisdictions as well. In addition, countries may refuse to reimburse or may restrict the reimbursed population for a product when their national health technology assessments do not consider a medicine to demonstrate sufficient clinical benefit beyond existing therapies or to meet certain cost effectiveness thresholds. For example, despite the EMA's approval of Repatha for the treatment of patients with established atherosclerotic disease, the reimbursement for Repatha in France prior to 2020 was limited to a narrower patient population (such as those with HoFH) following a national health technology assessment, which had limited our efforts in France to expand Repatha access to the broader patient population covered by the approved label. Some countries decide on reimbursement between potentially competing products through national or regional tenders that often result in one product receiving most or all of the sales in that country or region. Failure to obtain coverage and reimbursement for our products, a deterioration in their existing coverage and

reimbursement, or a decline in the timeliness or certainty of payment by payers to physicians and other providers has negatively affected, and may further negatively affect, the ability or willingness of healthcare providers to prescribe our products for their patients and otherwise negatively affect the use of our products or the prices we realize for them. Such changes have had, and could in the future have, a material adverse effect on our product sales, business and results of operations.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. Professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities. Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies. In addition, a growing number of organizations are providing assessments of the value and pricing of biopharmaceutical products, and even organizations whose guidelines have historically been focused on clinical matters have begun to incorporate analyses of the cost effectiveness of various treatments into their treatment guidelines and recommendations. Value assessments may come from private organizations that publish their findings and offer recommendations relating to the products' reimbursement by government and private payers. Some companies and payers have announced pricing and payment decisions based in part on the assessments of private organizations. In addition, government health technology assessment organizations in many countries make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service effects of new, emerging and existing medicines and treatments. Such health technology assessment organizations have recommended, and may in the future recommend, reimbursement for certain of our products for a narrower indication than was approved by applicable regulatory agencies or may recommend against reimbursement entirely. See *Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.* Such recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could have a material adverse effect on our product sales, business and results of operations. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price of our common stock.

The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability.

We are subject to income and other taxes in the United States and other jurisdictions in which we do business. As a result, our provision for income taxes is derived from a combination of applicable tax rates in the various places we operate. Significant judgment is required for determining our provision for income tax.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes can arise with tax authorities involving issues regarding the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and relevant facts, and such tax authorities (including the IRS) are becoming more aggressive in their audits and are particularly focused on such matters. In 2017, we received an RAR and a modified RAR from the IRS for the years 2010, 2011 and 2012, proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS administrative appeals office but were unable to reach resolution. In July 2021, we filed a petition in the U.S. Tax Court to contest two duplicate Statutory Notices of Deficiency (Notices) for 2010, 2011 and 2012 that we received in May and July 2021 which seek to increase our U.S. taxable income. We firmly believe that the IRS's positions set forth in the Notices are without merit, and are contesting the Notices through the judicial process. See Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations, Income Taxes, and Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

In 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015, also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS appeals office. We

were unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a statutory notice of deficiency for these years as well. We expect to contest any such notice related to 2013–15 through the judicial process. We are also currently under examination by the IRS for the years 2016, 2017 and 2018 and by a number of state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We continue to believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts

and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse effect on the results of our operations.

Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities and changes in applicable tax laws, regulations or administrative interpretations thereof. The 2017 Tax Act is complex and a large volume of regulations and guidance has been issued and could be subject to different interpretations. We could face audit challenges to our application of the 2017 Tax Act. The Administration proposed and Congress is considering significant changes to existing tax law. These changes, if enacted, could substantially increase taxes we pay to the U.S. government. Further, the OECD recently reached agreement to align countries on a minimum corporate tax rate and an expansion of the taxing rights of market countries. If enacted, this agreement could result in tax increases in both the United States and foreign jurisdictions.

The U.S. Treasury recently released final foreign tax credit regulations that eliminate U.S. creditability of the Puerto Rico Excise Tax beginning 2023, which will increase our U.S. tax liability. The U.S. territory of Puerto Rico is considering changes to its tax system that may minimize or eliminate this impact, but the outcome of such potential changes are uncertain. Changes to existing tax law in the United States, the U.S. territory of Puerto Rico, or other jurisdictions, including the potential changes discussed above, could result in tax increases where we do business and could have a material adverse effect on the results of our operations.

Our business may be affected by litigation and government investigations.

We and certain of our subsidiaries are involved in legal proceedings. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. Civil and criminal litigation is inherently unpredictable, and the outcome can result in costly verdicts, fines and penalties, exclusion from federal healthcare programs and/or injunctive relief that affect how we operate our business. Defense of litigation claims can be expensive, time consuming and distracting, and it is possible that we could incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our product sales, business and results of operations. In addition, product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention and could adversely affect our reputation and the demand for our products. We and certain of our subsidiaries have previously been named as defendants in product liability actions for certain of our products.

We are also involved in government investigations that arise in the ordinary course of our business. In recent years, there has been a trend of increasing government investigations and litigations against companies operating in our industry, both in the United States and around the world. See *Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.* Our business activities outside of the United States are subject to the FCPA and similar antibribery or anticorruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. We cannot ensure that all our employees, agents, contractors, vendors, licensees, partners or collaborators will comply with all applicable laws and regulations. On April 25, 2019, we entered into a settlement agreement with the DOJ and the OIG of the HHS to settle certain allegations relating to our support of independent charitable organizations that provide patients with financial assistance to access their medicines. As a result, we entered into a corporate integrity agreement with the OIG that requires us to maintain a corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years. While we expect to fully comply with all of our obligations under the corporate integrity agreement, failure to do so could result in substantial penalties and potential exclusion from government healthcare programs. We may also see new government investigations of or actions against us citing novel theories of recovery. For example, prosecutors are placing greater scrutiny on patient support programs, including commercial copay assistance programs, and further enforcement actions and investigations regarding such programs could limit our ability to provide co-pay assistance to commercial patients. Greater scrutiny has also been placed on sponsorships, speaker programs and other arrangements where healthcare professionals receive remuneration, travel or other value to participate in certain events, and further enforcement actions could limit our ability to participate in such arrangements. Any of these results could have a material adverse effect on our business and results of operations.

RISKS RELATED TO COMPETITION

Our products face substantial competition and our product candidates are also likely to face substantial competition.

We operate in a highly competitive environment. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We expect that our products and product candidates will compete with existing drugs, new drugs

currently in development, drugs currently approved for other indications that may later be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. Large pharmaceutical companies and generics manufacturers of pharmaceutical products have expanded into, and are expected to continue expanding into, the biotechnology field, and some pharmaceutical companies and generics manufacturers have formed partnerships to pursue biosimilars. With the proliferation of companies pursuing biopharmaceuticals, a number of our product candidates may enter markets with one or more competitors or with competitors soon to arrive. For example, several of our biosimilar products have entered into markets with one or more existing competitors. In addition, some of our competitors may have technical, competitive or other advantages over us for the development of technologies and processes or greater experience in particular therapeutic areas, and consolidation among pharmaceutical and biotechnology companies can enhance such advantages. These advantages may make it difficult for us to compete with them successfully to discover, develop and market new products and for our current products to compete with new products or new product indications they may bring to market. As a result, our products have been competing and may continue to compete, and our product candidates may compete, against products or product candidates that offer higher rebates or discounts, lower prices, equivalent or superior efficacy, better safety profiles, easier administration, earlier market availability or other competitive features. If we are unable to compete effectively, this could reduce sales, which could have a material adverse effect on our business and results of operations.

Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. Driven by cost pressures, efforts to limit or weaken patent protection for our industry are increasing. For example, the COVID-19 pandemic has resulted in increased interest in compulsory licenses, march-in rights or other governmental interventions, both in the United States and internationally, related to the procurement of drugs. See *The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, manufacturing, supply chains, distribution systems, product development, product sales, business and results of operations.* Third parties have challenged and may continue to challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. Challenges to patents may come from potential competitors or from parties other than those who seek to market a potentially-infringing product. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We have been in the past, are currently and expect to be in the future, involved in patent litigation. These matters have included, and may in the future include, litigation with manufacturers of products that purport to be biosimilars of certain of our products for patent infringement and for failure to comply with certain provisions of the BPCIA. A determination made by a court, agency or tribunal concerning infringement, validity, enforceability, injunctive or economic remedy, or the right to patent protection, for example, are typically subject to appellate or administrative review. Upon review, such initial determinations may be afforded little or no deference by the reviewing tribunal and may be affirmed, reversed or made the subject of reconsideration through further proceedings. A patent dispute or litigation has not discouraged, and may not in the future discourage, a potential violator from bringing the allegedly infringing product to market prior to a final resolution of the dispute or litigation. The period from inception until resolution of a patent dispute or litigation is subject to the availability and schedule of the court, agency or tribunal before which the dispute or litigation is pending. We have been, and may in the future be, subject to competition during this period and may not be able to recover fully from the losses, damages and harms we incur from infringement by the competitor product even if we prevail. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities, be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Further, under the Hatch–Waxman Act, our products approved by the FDA under the FDCA have been, and may in the future be, the subject of patent litigation with generics competitors before expiry of the five-year period of data exclusivity provided for under the Hatch-Waxman Act and prior to the expiration of the patents listed for the

product. Likewise, our innovative biologic products have been, and may in the future be, the subject of patent litigation prior to the expiration of our patents and, with respect to competitors seeking approval as a biosimilar or interchangeable version of our products, prior to the 12-year exclusivity period provided under the BPCIA. In addition, we have faced, and may in the future face, patent litigation involving claims that the biosimilar product candidates we are working to develop infringe the patents of other companies, including those that manufacture, market or sell the applicable reference products or who are developing or have developed other biosimilar versions of such products. Alternatively, patents held by other entities have contributed, and may in the future

contribute, to a decision by us to not pursue all of the same labeled indications as are held by these companies. Due to the COVID-19 pandemic, there have been delays in ongoing or new patent office and court proceedings in the United States and abroad that have delayed the outcome of such proceedings. While we have attempted, and expect to continue to attempt, to challenge the patents held by other companies, our efforts may be unsuccessful. For examples of and information related to our patent litigation, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Certain of the existing patents on our products have expired or will soon expire. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents. As our patents expire, competitors are able to legally produce and market similar products or technologies, including biosimilars, which has had, and may continue to have, a material adverse effect on our product sales, business and results of operations. In addition, competitors have been, and may continue to be, able to invalidate, design around or otherwise circumvent our patents and sell competing products.

We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.

We currently face competition from biosimilars and generics in most of the territories in which we operate, including the United States and Europe, and we expect to face increasing biosimilar and/or generics competition this year and beyond. Expiration or successful challenge of applicable patent rights or expiration of an applicable exclusivity period has accelerated such competition, and we expect to face more litigation regarding the validity and/or scope of our patents. Our products have also experienced greater competition from lower cost biosimilars or generics that come to market when branded products that compete with our products lose their own patent protection. To the extent that governments adopt more permissive regulatory approval standards and competitors are able to obtain broader or expedited marketing approval for biosimilars and generics, the rate of increased competition for our products could accelerate.

In the EU, biosimilars are evaluated for marketing authorization pursuant to a set of general and product class-specific guidelines. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU countries and some Canadian provinces have adopted, or are considering the adoption of, biosimilar uptake measures such as physician prescribing quotas or automatic pharmacy substitution of biosimilars for the corresponding reference products. Some EU countries impose automatic price reductions upon market entry of one or more biosimilar competitors. While the degree of competitive effects of biosimilar competition differs between EU countries and between products, in the EU the overall use of biosimilars and the rate at which product sales of innovative products are being affected by biosimilar competition is increasing.

In the United States, the BPCIA authorizes the FDA to approve biosimilars via a separate, abbreviated pathway. See Item 1. Business—Government Regulation—Regulation in the United States—Approval of Biosimilars. In the United States, the FDA has approved numerous biosimilars, including biosimilar versions of Neulasta, EPOGEN and ENBREL, and a growing number of companies have announced that they are also developing biosimilar versions of our products. Four biosimilar versions of Neulasta are now marketed in the United States, and we expect other biosimilar versions of Neulasta to receive approval in 2022 and beyond. Impact to our Neulasta sales has accelerated as additional competitors have launched. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. An approved biosimilar version of EPOGEN has also launched in the United States. Manufacturers of biosimilars have attempted, and may in the future attempt, to compete with our products by offering lower list prices, greater discounts or rebates, or contracts that offer longer-term pricing or a broader portfolio of other products. Companies pursuing development of biosimilar versions of our products have challenged and may continue to challenge our patents well in advance of the expiration of our material patents. For examples of and information related to our biosimilars and generics patent litigation, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. See *Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.*

The U.S. biosimilar pathway includes the option for biosimilar products that meet certain criteria to be approved as interchangeable with their reference products. Some companies currently developing or already marketing biosimilars may seek to obtain interchangeable status from the FDA, which could potentially allow pharmacists to substitute those biosimilars for our reference products without prior approval from the prescriber in most states. The FDA approved the first interchangeable biosimilar in July 2021, and subsequently granted an interchangeability designation to a second biosimilar in October 2021. In November 2019, the FDA issued draft guidance that provides that comparative immunogenicity studies will not generally be expected for biosimilar and

interchangeable insulin products. This may open the door for other product-specific guidance development and the removal of the expectation for certain studies, which may contribute to increased biosimilar competition for our innovative products. For example, the FDA 2021 guidance agenda lists four guidances related to biosimilars, including documents that address exclusivity for the first interchangeable biological product, and product class-specific recommendations for developing biosimilars and interchangeables.

In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law's provisions regarding which new

products receive data exclusivity. In late 2019, the previous Administration agreed to remove from the United States-Mexico-Canada Agreement a requirement for at least 10 years of data exclusivity for biologic products. Also, the FDA is considering whether subsequent changes to a licensed biologic would be protected by the remainder of the reference product's original 12-year exclusivity period (a concept known in the generic drug context as "umbrella exclusivity"). If the FDA were to decide that umbrella exclusivity does not apply to biological reference products or were to make other changes to the exclusivity period, this could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, legislative and regulatory efforts to promote competition through policies enabling easier generic and biosimilar approval and commercialization, including efforts to lower standards for demonstrating biosimilarity or interchangeability, limit patents that may be litigated and/or patent settlements, implement preferential reimbursement policies for biosimilars and pass new laws requiring more disclosure in the FDA's Orange and Purple Books. For example, in 2021 the FDA sent a letter to the USPTO describing ways to strengthen coordination between the two agencies, offered training to help identify prior art, and seeking USPTO's views on practices that extend market exclusivities, whether pharmaceutical patent examiners need additional resources, and the effect of post-grant challenges at the PTAB on drug patents.

Upon the expiration or loss of patent protection and/or applicable exclusivity for one of our small molecule products, we can lose the majority of revenues for that product in a very short period of time. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. Additionally, if one of our small molecule products is the subject of an FDA Written Request for pediatric studies and we are unable to adequately complete these studies, we may not obtain the pediatric exclusivity award that extends existing patents and unexpired regulatory exclusivity for the product by an additional six months.

While we are unable to predict the precise effects of biosimilars and generics on our products, we are currently facing and expect to face greater competition in the United States, Europe and elsewhere as a result of biosimilar and generic competition and, in turn, downward pressure on our product prices and sales. This competition has had, and could increasingly have, a material adverse effect on our product sales, business and results of operations. State laws may also have an impact on our business. For example, California is the first state to have passed legislation, effective on January 1, 2020, against "pay for delay" settlements of patent infringement claims filed by manufacturers of generics or biosimilars where anything of value is given in exchange for settlement. Under this law, such settlement agreements are presumptively anticompetitive. The law may result in prolonged litigation and fewer settlements. Other states, including Connecticut, New York, Illinois and Minnesota, may adopt similar laws or a similar law could be adopted at the federal level.

Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively affect our business.

Certain of our distributors, customers and payers have substantial purchasing leverage, due to the volume of our products they purchase or the number of patient lives for which they provide coverage. The substantial majority of our U.S. product sales is made to three pharmaceutical product wholesaler distributors: McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc. These distributors, in turn, sell our products to their customers, which include physicians or their clinics, dialysis centers, hospitals and pharmacies. One of our products, EPOGEN, is sold primarily to free-standing dialysis clinics. DaVita owns or manages a large number of the outpatient dialysis facilities located in the United States and accounts for approximately 90% of all EPOGEN sales. Similarly, as discussed above, there has been significant consolidation in the health insurance industry, including that a small number of PBMs now oversee a substantial percentage of total covered lives in the United States. See *Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.* The three largest PBMs in the United States are now part of major health insurance providers. The growing concentration of purchasing and negotiating power by these entities has, and may continue to, put pressure on our pricing due to their ability to extract price discounts on our products, fees for other services or rebates, negatively affecting our bargaining position, sales and/or profit margins. In addition, decisions by these entities to purchase or cover less or none of our products in favor of competing products could have a material adverse effect on our product sales, business and results of operations due to their purchasing volume. Further, if one of our significant wholesale distributors encounters financial or other difficulties and becomes unable or unwilling to pay us all amounts that such distributor owes us on a timely basis, or at all, it could negatively affect our business and results of operations. In addition, if one of our significant wholesale distributors becomes insolvent or otherwise unable to continue its commercial relationship with us in its present form, it could significantly disrupt our business and adversely affect our product sales, our business and results of operations unless suitable alternatives are timely found or lost sales are absorbed by another distributor.

RISKS RELATED TO RESEARCH AND DEVELOPMENT

We may not be able to develop commercial products despite significant investments in R&D.

Amgen invests heavily in R&D. Successful product development in the biotechnology industry is highly uncertain, and very few R&D projects yield approved and commercially viable products. Product candidates, including biosimilar product

candidates, or new indications for existing products (collectively, product candidates) that appear promising in the early phases of development have failed to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it achieved its primary endpoints and/or demonstrated positive preclinical or early clinical trial results, for reasons that could include changes in the standard of care of medicine or expectations of health authorities;
- the product candidate was not effective or not more effective than currently available or potentially competitive therapies in treating a specified condition or illness;
- the product candidate was not cost effective in light of existing or potentially competitive therapeutics;
- the product candidate had harmful side effects in animals or humans;
- the necessary regulatory bodies, such as the FDA or EMA, did not approve the product candidate for an intended use;
- reimbursement for the product candidate is limited despite regulatory approval;
- the product candidate was not economical for us to manufacture and commercialize;
- other parties had or may have had proprietary rights relating to our product candidate, such as patent rights, and did not let us sell it on reasonable terms, or at all;
- we and certain of our licensees, partners, contracted organizations or independent investigators failed to effectively conduct clinical development or clinical manufacturing activities;
- the pathway to regulatory approval or reimbursement for product candidates was uncertain or not well-defined;
- the biosimilar product candidate failed to demonstrate the requisite biosimilarity to the applicable reference product, or was otherwise determined by a regulatory authority to not meet applicable standards for approval; and
- a companion diagnostic device that is required with the use of a product candidate is not approved by the necessary regulatory authority.

We have spent considerable time, energy and resources developing our expertise in human genetics and acquiring access to libraries of genetic information with the belief that genetics could meaningfully aid our search for new medicines and help guide our R&D decisions and investments. We have focused our R&D strategy on drug targets validated by genetic or other compelling human evidence. However, product candidates based on genetically validated targets remain subject to the uncertainties of the drug development process and may not reach the market for a number of reasons, including the factors listed above.

We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.

Before a product may be sold, we must conduct clinical trials to demonstrate that our product candidates are safe and effective for use in humans. The results of those clinical trials are used as the basis to obtain approval from regulatory authorities such as the FDA and EMA. See *Our current products and products in development cannot be sold without regulatory approval*. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims. The length of time, number of trial sites and number of patients required for clinical trials vary substantially, and we may spend several years and incur substantial expense in completing certain clinical trials. In addition, we may have difficulty finding a sufficient number of clinical trial sites and patients to participate in our clinical trials, particularly if competitors are conducting clinical trials in similar patient populations. See *The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations.* Patients may withdraw from clinical trials at any time, and privacy laws and/or other restrictions in certain countries may restrict the ability of clinical trial investigators to conduct further follow-up on such patients, which may adversely affect the interpretation of study results. Delays and complications in planned clinical trials can result in increased development costs, associated delays in regulatory approvals and in product candidates reaching the market and revisions to existing product labels.

Further, to increase the number of patients available for enrollment in our clinical trials, we have opened, and will continue to open, clinical sites and enroll patients in a number of locations where our experience conducting clinical trials is more limited, including Russia, India, China, South Korea, the Philippines, Singapore and some Central and South American countries, either through utilization of third-party contract clinical trial providers entirely or in combination with local staff.

Conducting clinical trials in locations where we have limited experience requires substantial time and resources to understand the unique regulatory environments of individual countries. For other examples of the risks of conducting clinical trials in China, see also *Our sales and operations are subject to the risks of doing business internationally, including in emerging markets*. Further, we must ensure the timely production, distribution and delivery of the clinical supply of our product candidates to numerous and varied clinical trial sites. Additionally, regional disruptions, including natural and man-made disasters or health emergencies (such as novel viruses or pandemics such as the one we are currently experiencing with COVID-19), have significantly disrupted, and in the future could disrupt, the timing of clinical trials. If we fail to adequately manage the design, execution and diverse regulatory aspects of our large and/or complex clinical trials or to manage the production or distribution of our clinical supply, or such sites experience disruptions as a result of a natural/man-made disaster or health emergency, corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates or could lose our ability to market existing products in certain therapeutic areas or altogether. For example, our clinical trials have been adversely affected by the COVID-19 pandemic. See *The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations.* If we are unable to market and sell our products or product candidates or to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations could be materially and adversely affected.

We rely on independent third-party clinical investigators to recruit patients and conduct clinical trials on our behalf in accordance with applicable study protocols, laws and regulations. Further, we rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations. In some circumstances, we enter into co-development arrangements with other pharmaceutical and medical devices companies that provide for the other company to conduct certain clinical trials for the product we are co-developing or to develop a diagnostic test used in screening or monitoring patients in our clinical trials. See *Some of our pharmaceutical pipeline and our commercial product sales rely on collaborations with third parties, which may adversely affect the development and sale of our products.* We also may acquire companies that have past or ongoing clinical trials or rights to products or product candidates for which clinical trials have been or are being conducted. These trials may not have been conducted to the same standards as ours; however, once an acquisition has been completed we assume responsibility for the conduct of these trials, including any potential risks and liabilities associated with the past and prospective conduct of those trials. If regulatory authorities determine that we or others, including our licensees or co-development partners, or the independent investigators or vendors selected by us, our co-development partners or by a company we have acquired or from which we have acquired rights to a product or product candidate, have not complied with regulations applicable to the clinical trials, those authorities may refuse or reject some or all of the clinical trial data or take other actions that could delay or otherwise negatively affect our ability to obtain or maintain marketing approval of the product or indication. In addition, delays or failures to develop diagnostic tests for our clinical trials can affect the timely enrollment of such trials and lead to delays or inability to obtain marketing approval. If we were unable to market and sell our products or product candidates, our business and results of operations could be materially and adversely affected.

In addition, some of our clinical trials utilize drugs manufactured and marketed by other pharmaceutical companies. These drugs may be administered in clinical trials in combination with one of our products or product candidates or in a head-to-head study comparing the products' or product candidates' relative efficacy and safety. In the event that any of these vendors or pharmaceutical companies have unforeseen issues that negatively affect the quality of their work product or create a shortage of supply, or if we are otherwise unable to obtain an adequate supply of these other drugs, our ability to complete our applicable clinical trials and/or evaluate clinical results may also be negatively affected. As a result, such quality or supply problems could adversely affect our ability to timely file for, gain or maintain regulatory approvals worldwide.

Clinical trials must generally be designed based on the current standard of medical care. However, in certain diseases, such as cancer, the standard of care is evolving rapidly. In some cases, we may design a clinical trial based on the standard of care we anticipate will exist at the time our study is completed. The duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on standards of medical care that are no longer or that have not become the current standards by the time such trials are completed, limiting the utility and application of such trials. Additionally, the views of regulatory agencies relating to the requirements for accelerated approval may change over time, and trial designs that were sufficient to support accelerated approvals for some oncology products may not be considered sufficient for later candidates. We may not obtain favorable clinical trial results and therefore may not be able to obtain regulatory approval for new product candidates or new

indications for existing products and/or maintain our current product labels. Participants in clinical trials of our products and product candidates may also suffer adverse medical events or side effects that could, among other factors, delay or terminate clinical trial programs and/or require additional or longer trials to gain approval.

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a risk management plan for our product or for approval of a new indication. Additional clinical trials we initiate, including those required by the FDA, could result in substantial additional expense, and the outcomes could result in further label restrictions or

the loss of regulatory approval for an approved indication, each of which could have a material adverse effect on our product sales, business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our products, our business and results of operations.

Our current products and products in development cannot be sold without regulatory approval.

Our business is subject to extensive regulation by numerous state and federal government authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in the other regions and countries in which we, or our partners and affiliates, sell to obtain approval from regulatory authorities before we manufacture, market and sell our products. Once our products are approved, the FDA and other U.S. and ex-U.S. regulatory agencies have substantial authority to require additional testing and reporting, perform inspections, change product labeling or mandate withdrawals of our products. Failure to comply with applicable regulatory requirements may subject us to administrative and/or judicially imposed sanctions or monetary penalties as well as reputational and other harms. The sanctions could include the FDA's or ex-U.S. regulatory authorities' refusals to approve pending applications, delays in obtaining or withdrawals of approvals, delays or suspensions of clinical trials, warning letters, product recalls or seizures, total or partial suspensions of our operations, injunctions, fines, civil penalties and/or criminal prosecutions.

Obtaining and maintaining regulatory approvals have been, and will continue to be, increasingly difficult, time-consuming and costly. Legislative bodies or regulatory agencies could enact new laws or regulations, change existing laws or regulations or change their interpretations of laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products or product candidates. The rate and degree of change in existing laws and regulations and regulatory expectations have accelerated in established markets, and regulatory expectations continue to evolve in emerging markets. We are unable to predict whether and when any further changes to laws or regulatory policies affecting our business could occur, such as changes to laws or regulations governing manufacturer communications concerning drug products and drug product candidates and whether such changes could have a material adverse effect on our product sales, business and results of operations. Further, we are reliant on regulators having the resources necessary to evaluate and approve our products. In the United States, a partial federal government shutdown halted the work of many federal agencies and their employees from late December 2018 through late January 2019. A subsequent extended shutdown could result in reductions or delays of FDA's activities, including with respect to our ongoing clinical programs, our manufacturing of our products and product candidates and our product approvals.

Regulatory authorities have questioned, and may in the future question, the sufficiency for approval of the endpoints we select for our clinical trials. A number of our products and product candidates have been evaluated in clinical trials using surrogate endpoints that measure an effect that is known to correlate with an ultimate clinical benefit. For example, a therapeutic oncology product candidate may be evaluated for its ability to reduce or eliminate MRD, or to extend the length of time during and after the treatment that a patient lives without the disease worsening, measured by PFS. Demonstrating that the product candidate induces MRD-negative responses or produces a statistically significant improvement in PFS does not necessarily mean that the product candidate will show a statistically significant improvement in overall survival or the time that the patients remain alive. In the CV setting, a heart disease therapeutic candidate may be evaluated for its ability to reduce LDL-C levels, as an elevated LDL-C level has been a surrogate endpoint for CV events such as death, heart attack and stroke. The use of surrogate endpoints such as PFS and LDL-C reduction, in the absence of other measures of clinical benefit, may not be sufficient for broad usage or approval even when such results are statistically significant. Regulatory authorities could also add new requirements, such as the completion of enrollment in a confirmatory study or the completion of an outcomes study or a meaningful portion of an outcomes study, as conditions for obtaining approval or obtaining an indication. For example, despite demonstrating that Repatha reduced LDL-C levels in a broad patient population, only after our large phase 3 outcomes study evaluating the ability of Repatha to prevent CV events met certain of its primary composite endpoint and key secondary composite endpoint did the FDA grant a broader approval of Repatha to reduce the risk of certain CV events. There may also be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to other existing treatment options can be shown. The imposition of additional requirements or our inability to meet them in a timely fashion, or at all, has delayed, and may in the future delay, our clinical development and regulatory filing efforts, delay or prevent us from obtaining regulatory approval for new product candidates or new indications for existing products, or prevent us from maintaining our current product labels.

Some of our products have been approved by U.S. and ex-U.S. regulatory authorities on an accelerated or conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, in March 2018, we announced that the FDA approved BLINCYTO under accelerated approval for the treatment of certain patients with B-cell precursor ALL. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Regulatory authorities are placing greater focus on monitoring products originally approved on an accelerated or conditional basis and on whether the sponsors of such products have met the conditions of the accelerated or conditional approvals. If we are unable to fulfill the regulators' requirements that were conditions of a product's accelerated or conditional approval and/or if regulators reevaluate the data or risk-benefit profile of our product, the conditional approval may not result in

full approval or may be revoked or not renewed. Alternatively, we may be required to change the product's labeled indications or even withdraw the product from the market.

Regulatory authorities can also impose post-marketing pediatric study requirements. Failure to fulfill such requirements may result in regulatory or enforcement action, including financial penalties or the invalidation of a product's marketing authorization.

Safety problems or signals can arise as our products and product candidates are evaluated in clinical trials, including investigator sponsored studies, or as our marketed products are used in clinical practice. We are required continuously to collect and assess adverse events reported to us and to communicate to regulatory agencies these adverse events and safety signals regarding our products. Regulatory agencies periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. In the United States, for our products with approved REMS (see Item 1. Business—Government Regulation—Postapproval Phase), we are required to submit periodic assessment reports to the FDA to demonstrate that the goals of the REMS are being met. REMS and other risk management programs are designed to ensure that a drug's benefits outweigh the risks and vary in the elements they contain. If the FDA is not satisfied with the results of the periodic assessment reports we submit for any of our REMS, the FDA may also modify our REMS or take other regulatory actions, such as implementing revised or restrictive labeling. The drug delivery devices approved for use in combination with our products are also subject to regulatory oversight and review for safety and malfunctions. See *Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.* If regulatory agencies determine that we or other parties (including our clinical trial investigators, those operating our patient support programs or licensees of our products) have not complied with the applicable reporting, other pharmacovigilance or other safety or quality assessment requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including fines, marketing authorization withdrawal and other penalties. Our product candidates and marketed products can also be affected by safety problems or signals occurring with respect to products that are similar to ours or that implicate an entire class of products. Further, as a result of clinical trials, including sub-analyses or meta-analyses of earlier clinical trials (a meta-analysis involves the use of various statistical methods to combine results from previous separate but related studies) performed by us or others, concerns may arise about the sufficiency of the data or studies underlying a product's approved label. Such actual or perceived safety problems or concerns can lead to:

- revised or restrictive labeling for our products, or the potential for restrictive labeling that has resulted, and may in the future result, in our decision not to commercialize a product candidate;
- requirement of risk management or minimization activities or other regulatory agency compliance actions related to the promotion and sale of our products;
- post-marketing commitments, mandated post-marketing requirements or pharmacovigilance programs for our approved products;
- product recalls of our approved products;
- required changes to the processes used in the manufacture of our products, which could increase our manufacturing costs and affect the availability of contract manufacturers we may utilize to assist in such manufacturing;
- revocation of approval for our products from the market completely, or within particular therapeutic areas or patient types;
- increased timelines or delays in being approved by the FDA or other regulatory bodies; and/or
- treatments or product candidates not being approved by regulatory bodies.

For example, after an imbalance in positively adjudicated CV serious adverse events was observed in one of the phase 3 clinical trials for EVENITY but not in another, larger phase 3 study, in April 2019 the FDA approved EVENITY for the treatment of osteoporosis in postmenopausal women at high risk for fracture, along with a post-marketing requirement. The requirement includes a five-year observational feasibility study that could be followed by a comparative safety study or trial.

In addition to our innovative products, we are working to develop and commercialize biosimilar versions of a number of products currently manufactured, marketed and sold by other pharmaceutical companies. In some markets,

there is not yet a legislative or regulatory pathway for the approval of biosimilars. In the United States, the BPCIA provided for such a pathway; while the FDA continues to develop regulatory and scientific policies for biosimilars, discussions continue as to the evidence needed to demonstrate biosimilarity or interchangeability for specific products. See *We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.* Delays or uncertainties in the development or implementation of such pathways, or changes in existing regulatory pathways, including degradation of regulatory standards, could result in delays or difficulties in getting our biosimilar products approved by regulatory authorities, subject us to unanticipated development costs or otherwise reduce the value of the investments we have

made in the biosimilars area. Further, we cannot predict whether any repeal or reform of the ACA or other legislation or policy initiatives would affect the biosimilar pathway or have a material adverse effect on our development of biosimilars or on our marketed biosimilars. In addition, if we are unable to bring our biosimilar products to market on a timely basis and secure "first-to-market" or other advantageous positions, our future biosimilar sales, business and results of operations could be materially and adversely affected.

Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.

Many of our products and product candidates may be used in combination with a drug delivery device, such as an injector or other delivery system. For example, Neulasta is available as part of the Neulasta Onpro kit, and our AutoTouch reusable autoinjector is used with ENBREL Mini single-dose prefilled cartridges. In addition, some of our products or product candidates, including many of our oncology product candidates and products, including LUMAKRAS, may also require the use of a companion or other diagnostic device such as a device that determines whether the patient is eligible to use our drug or that helps ensure its safe and effective use. In some regions, including the United States, regulatory authorities may require contemporaneous approval of the companion diagnostic device and the therapeutic product; in others the regulatory authorities may require a separate study of the companion diagnostic device. Our product candidates or expanded indications of our products used with such devices may not be approved or may be substantially delayed in receiving regulatory approval if development or approval of such devices is delayed, such devices do not also gain or maintain regulatory approval or clearance, or if such devices do not remain commercially available. When approval of the product and device is sought under a single marketing drug application, the increased complexity of the review process may delay receipt of regulatory approval. In addition, some of these devices may be provided by single-source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies to supply and/or market the devices and, in some cases, to conduct the studies required for approval or clearance by the applicable regulatory agencies. We are also dependent on those third-party companies continuing to meet applicable regulatory or other requirements. Failure to successfully develop, modify, or supply the devices, delays in or failures of the Amgen or third-party studies, or failure of us or the third-party companies to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs; delays in, or failure to obtain or maintain, regulatory approval; and/or associated delays in a product candidate reaching the market or in the addition of new indications for existing products. We are also required to collect and assess user complaints, adverse events and malfunctions regarding our devices, and actual or perceived safety problems or concerns with a device used with our product can lead to regulatory actions and adverse effects on our products. See *Our current products and products in development cannot be sold without regulatory approval*. Additionally, regulatory agencies conduct routine monitoring and inspections to identify and evaluate potential issues with our devices. For example, in 2017, the FDA reported on its adverse event reporting system that it was evaluating our Neulasta Onpro kit. Subsequently, we implemented device and labeling enhancements to address product complaints received on this device. We continuously monitor complaints and adverse events and implement additional enhancements as needed. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop, supply, or gain or maintain approval for these devices could adversely affect sales of the related approved products.

Some of our pharmaceutical pipeline and our commercial product sales rely on collaborations with third parties, which may adversely affect the development and sale of our products.

We depend on alliances with other companies, including pharmaceutical and biotechnology companies, vendors and service providers, for the development of a portion of the products in our pharmaceutical pipeline and for the commercialization and sales of certain of our commercial products. For example, we have collaborations with third parties under which we share development rights, obligations and costs and/or commercial rights and obligations. See Item 1. Business—Business Relationships.

Failures by these parties to meet their contractual, regulatory, or other obligations to us or any disruption in the relationships between us and these third parties, could have a material adverse effect on our pharmaceutical pipeline and business. In addition, our collaborative relationships for R&D and/or commercialization and sales often extend for many years and have given, and may in the future give, rise to disputes regarding the relative rights, obligations and revenues of us and our collaboration partners, including the ownership or prosecution of intellectual property and associated rights and obligations. This could result in the loss of intellectual property rights or protection, delay the

development and sale of potential pharmaceutical products, affect the effective sale and delivery of our commercialized products and lead to lengthy and expensive litigation, administrative proceedings or arbitration.

Our efforts to collaborate with or acquire other companies, products, or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.

We seek innovation through significant investment in both internal R&D and external transactions, including collaborations, partnering, alliances, licenses, joint ventures, mergers and acquisitions (collectively, acquisition activity). Acquisition activities may be subject to regulatory approvals or other requirements that are not within our control. There can be no assurance that such regulatory or other approvals will be obtained or that all closing conditions required in connection with our acquisition activities will be satisfied or waived, which could result in us being unable to complete the planned acquisition activities.

Acquisition activities are complex, time consuming and expensive and may result in unanticipated costs, delays or other operational or financial problems related to integrating the acquired company and business with our company, which may divert our management's attention from other business issues and opportunities and restrict the full realization of the anticipated benefits of such transactions within the expected timeframe or at all. We may pay substantial amounts of cash, incur debt or issue equity securities to pay for acquisition activities, which could adversely affect our liquidity or result in dilution to our stockholders, respectively. Further, failures or difficulties in integrating or retaining new personnel or in integrating the operations of the businesses, products or assets we acquire (including related technology, commercial operations, compliance programs, manufacturing, distribution and general business operations and procedures) may affect our ability to realize the benefits of the transaction and grow our business and may result in us incurring asset impairment or restructuring charges. These and other challenges may arise in connection with our acquisition of Otezla, Five Prime, Teneobio and/or our collaborations with BeiGene and KKC, or with other acquisition activities, which could have a material adverse effect on our business, results of operations and stock price.

RISKS RELATED TO OPERATIONS

We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.

The global supply of our products and product candidates for commercial sales and for use in our clinical trials is significantly dependent on the uninterrupted and efficient operation of our manufacturing facilities, in particular those in the U.S. territory of Puerto Rico and Thousand Oaks, California. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

We currently perform a substantial majority of our clinical manufacturing that supports our product candidates at our facility in Thousand Oaks, California. A substantial disruption in our ability to operate our Thousand Oaks manufacturing facility could materially and adversely affect our ability to supply our product candidates for use in our clinical trials, leading to delays in development of our product candidates.

In addition, we currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico. In recent years, Puerto Rico has been affected by natural disasters, including droughts in mid-2020, earthquakes in early 2020 and Hurricane Maria in 2017. These natural disasters have affected, and may continue to affect, public and private properties and Puerto Rico's electric grid and communications networks in the future. While the critical manufacturing areas of our commercial manufacturing facility were not significantly affected by these natural disasters, the restoration of electrical service on the island after Hurricane Maria was a slow process, and our facility operated with electrical power from backup diesel powered generators for some time. We also operated on backup generators for a few weeks after the early 2020 earthquakes in Puerto Rico. In 2021, the baseload power generation units of the Puerto Rico Electric Power Authority malfunctioned due to the lack of adequate maintenance for over a decade. The problems experienced by these units, which are among the oldest in North America, have led to selective outages across the island. Further instability of the electric grid and unreliability on the generation units could require us to increase the use of our generators or to continue using them exclusively. In addition, future storms, earthquakes or other natural disasters or events could cause a more significant effect on our manufacturing operations. Puerto Rico and the rest of the world are facing the effects of the COVID-19 pandemic and the associated health and economic implications. In March 2020, the Governor of Puerto Rico issued Executive Orders requiring the lockdown of businesses and government facilities, imposing restrictions on business operations and a curfew on residents. Our operations and employees were

exempted from the lockdown and curfew, but we cannot predict whether the Governor will issue future Executive Orders imposing stricter lockdown and curfew measures should COVID-19 cases rise in Puerto Rico. Additionally, during the summer of 2021, a labor dispute arose between the maritime terminal operation company and its employees, represented by the International Longshoremen's Association (ILA), which resulted in a strike that delayed cargo movement from the San Juan Port Zone for several days. Although our ability to manufacture and supply our products has not,

to date, been significantly affected by these natural disasters, the unreliability of the electric service, the ILA strike or the COVID-19 pandemic, a combination of these challenges or other issues that could give rise to any substantial disruption to our ability to operate our Puerto Rico manufacturing facility or get supplies and manufactured products transported to and from that location could materially and adversely affect our ability to supply our products and affect our product sales. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

Hurricane Maria, the earthquakes of early 2020 and the COVID-19 pandemic have placed greater stress on the island's already challenged economy. Beginning in 2016, the government of Puerto Rico defaulted on its roughly $72 billion in debt. In response, the U.S. Congress passed the PROMESA, which established the FOMBPR to provide fiscal oversight. Title III of PROMESA provides Puerto Rico with a judicial process for restructuring its debt similar to, but not identical to, Chapter 9 of the U.S. Bankruptcy Code, including a stay of debtholder litigation. In 2017, the FOMBPR approved and certified the filing in the U.S. District Court for the District of Puerto Rico of a voluntary petition under Title III of PROMESA for the government of Puerto Rico and certain of its governmental entities, including the Puerto Rico Electric Power Authority, which recently privatized its transmission and distribution infrastructure. After years of negotiations with bondholders and other creditors, the FOMBPR reached an agreement with the same and presented a Plan of Adjustment to the Title III Court. The Plan of Adjustment requires the Puerto Rico government to enact legislation authorizing the issuance of new bonds in exchange for older bonds and a reduction of the U.S. territory's debt. On October 26, 2021, Act 53-2021, known as the "Law to End the Bankruptcy of Puerto Rico," was enacted. From November to December 2021, the Court held several hearings regarding the approval of the Plan of Adjustment, and the Modified Eighth Plan of Adjustment was confirmed by the Court on January 18, 2022, to be effective on March 15, 2022.

Each year since 2017, the FOMBPR has updated Puerto Rico's fiscal plans implementing various measures intended to achieve fiscal responsibility and to restore Puerto Rico's access to the capital markets, including significant expense reductions and suggested measures for economic growth. Each plan has stressed the need for fiscal and structural reforms to address Puerto Rico's challenging economic and demographic trends. However, the government has not made significant progress during 2021 on the implementation of the fiscal and structural reforms required in the fiscal plan, in part due to the COVID-19 pandemic.

While the government and the FOMBPR have authorized emergency relief packages due to the COVID-19 pandemic, it is uncertain how, or the degree to which, the pandemic will impact Puerto Rico's fiscal and structural reforms and its economy. In addition, the 2017 Tax Act no longer permits deferral of U.S. taxation on Puerto Rico earnings, although these earnings generally will be taxed in the United States at a reduced rate. Given Puerto Rico's challenged economy, disaster recovery needs and impact from the COVID-19 pandemic, it may be difficult for Puerto Rico to sustain or grow its manufacturing base, which contributes significantly to Puerto Rico's economy, due to competition from other locations subject to similar levels of taxation.

While PROMESA and the actions above continue to be important factors in moving Puerto Rico toward economic stability, Puerto Rico's ongoing economic and demographic trend challenges and political situation, the effects of natural disasters, the unreliability of its electric system, the COVID-19 pandemic and the effects of the 2017 Tax Act or other potential tax law changes have negatively affected, and may in the future negatively affect, the territorial government's provision of utilities or other services in Puerto Rico that we use in the operation of our business and could create the potential for increased taxes or fees to operate in Puerto Rico, result in a migration of workers from Puerto Rico to the mainland United States, or make it more expensive or difficult for us to operate in Puerto Rico. These factors could have a material adverse effect on our ability to supply our products, on our business and on our product sales.

We rely on third-party suppliers for certain of our raw materials, medical devices and components.

We rely on unaffiliated third-party suppliers for certain raw materials, medical devices and components necessary for the manufacturing of our commercial and clinical products. Certain of those raw materials, medical devices and components are proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug applications with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until the regulatory agency approved such supplier. For example, we rely on a single source for the SureClick autoinjectors used in the drug delivery of Repatha, ENBREL, Aimovig, AMGEVITA and Aranesp. Also, certain of the raw materials required in the commercial and clinical manufacturing of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues, bovine serum and human serum albumin.

Among the reasons we may be unable to obtain these raw materials, medical devices and components include:

- regulatory requirements or action by regulatory agencies or others;
- adverse financial or other strategic developments at or affecting the supplier, including bankruptcy;
- unexpected demand for or shortage of raw materials, medical devices or components;

- failure to comply with our quality standards which results in quality and product failures, product contamination and/or recall;
- a material shortage, contamination, recall and/or restrictions on the use of certain biologically derived substances or other raw materials;
- discovery of previously unknown or undetected imperfections in raw materials, medical devices or components;
- cyberattacks on supplier systems; and
- labor disputes or shortages, including from the effects of health emergencies (such as novel viruses or pandemics such as the one we are currently experiencing with COVID-19) and natural disasters.

For example, in prior years we have experienced shortages in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility. Further quality issues that result in unexpected additional demand for certain components have resulted in shortages, and in the future may lead to shortages, of required raw materials or components (such as we have experienced with EPOGEN glass vials). We may experience similar or other shortages in the future resulting in delayed shipments, supply constraints, clinical trial delays, contract disputes and/or stock-outs of our products. These or other similar events could negatively affect our ability to satisfy demand for our products or conduct clinical trials, which could have a material adverse effect on our product sales, business and results of operations.

Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

Manufacturing biologic and small molecule human therapeutic products is difficult, complex and highly regulated. We manufacture many of our commercial products and product candidates internally. In addition, we currently use third-party contract manufacturers to produce, or assist in the production of, a number of our products, and we currently use contract manufacturers to produce, or assist in the production of, a number of our late-stage product candidates and drug delivery devices. See Item 1. Business—Manufacturing, Distribution and Raw Materials —Manufacturing. Our ability to adequately and timely manufacture and supply our products (and product candidates to support our clinical trials) is dependent on the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers, which may be affected by:

- capacity of manufacturing facilities;
- contamination by microorganisms or viruses, or foreign particles from the manufacturing process;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of health emergencies (such as novel viruses or pandemics such as the one we are currently experiencing with COVID-19) or natural disasters;
- compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs and production success rates and yields;
- updates of manufacturing specifications;
- contractual disputes with our suppliers and contract manufacturers;
- timing and outcome of product quality testing;
- power failures and/or other utility failures;
- cyberattacks on supplier systems;
- breakdown, failure, substandard performance or improper installation or operation of equipment (including our information technology systems and network-connected control systems or those of our contract manufacturers or third-party service providers); and/or
- delays in the ability of the FDA or foreign regulatory agencies to provide us necessary reviews, inspections and approvals, including as a result of a subsequent extended U.S. federal or other government shutdowns.

If any of these or other problems affect production in one or more of our facilities or those of our third-party contract manufacturers, or if we do not accurately forecast demand for our products or the amount of our product candidates required in

clinical trials, we may be unable to start or increase production in our unaffected facilities to meet demand. If the efficient manufacture and supply of our products or product candidates is interrupted, we may experience delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends, contract disputes and/or recalls of our products. From time to time, we have initiated recalls of certain lots of our products. For example, in July 2014 we initiated a voluntary recall of an Aranesp lot distributed in the EU after particles were detected in a quality control sample following distribution of that lot, and in April 2018 we initiated a precautionary recall of two batches of Vectibix distributed in Switzerland after potential crimping defects were discovered in the metal seals on some product vials. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could have a material adverse effect on our product sales, business and results of operations.

Our manufacturing processes, those of our third-party contract manufacturers and those of certain of our third-party service providers must undergo regulatory approval processes and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build, validate and license another manufacturing plant, and it can take longer than three years to qualify and license a new contract manufacturer or service provider. If we elect or are required to make changes to our manufacturing processes because of new regulatory requirements, new interpretations of existing requirements or other reasons, this could increase our manufacturing costs and result in delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends or contract negotiations or disputes. Such manufacturing challenges may also occur if our existing contract manufacturers are unable or unwilling to timely implement such changes, or at all.

In addition, regulatory agencies conduct routine monitoring and inspections of our manufacturing facilities and processes as well as those of our third-party contract manufacturers and service providers. If regulatory authorities determine that we or our third-party contract manufacturers or certain of our third-party service providers have violated regulations, they may mandate corrective actions and/or issue warning letters, or even restrict, suspend or revoke our prior approvals, prohibiting us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. See also *Our current products and products in development cannot be sold without regulatory approval.* Such issues may also delay the approval of product candidates we have submitted for regulatory review, even if such product candidates are not directly related to the products, devices or processes at issue with regulators. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis, or at all. If we or our third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers fail to supply materials, products or services to us, we may experience delayed shipments, delays in our clinical trials, supply constraints, contract disputes, stock-outs and/or recalls of our products. Additionally, we distribute a substantial volume of our commercial products through our primary distribution centers in Louisville, Kentucky for the United States and in Breda, Netherlands for Europe and much of the rest of the world. We also conduct most of the labeling and packaging of our products distributed in Europe and much of the rest of the world in Breda. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics centers, our third-party logistics providers and our labeling and packaging facility in Breda. Further, we rely on commercial transportation, including air and sea freight, for the distribution of our products to our customers, which may be negatively affected by natural disasters, security threats and/or the ongoing COVID-19 pandemic.

There have also been legislative and administrative proposals seeking to incentivize greater drug manufacturing in the United States with the stated goal of improving supply reliability in the United States. For example, on August 6, 2020, the previous Administration issued an Executive Order aimed at boosting domestic production of essential medicines, medical countermeasures, and critical inputs titled “Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs are Made in the United States.” Additionally, one legislative proposal would prohibit the U.S. Department of Veterans Affairs from purchasing certain drugs that have active pharmaceutical ingredients manufactured outside the United States. While we perform a substantial majority of our commercial manufacturing activities in the United States, including in the U.S. territory of Puerto Rico, and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California, the passage of such legislation could result in foreign governments enacting retaliatory legislation or regulatory actions, which may have an adverse effect on our product sales, business and results of operations.

Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives.

We continue to work towards operating our business in an environmentally responsible and socially inclusive manner. Stakeholders, including our investors and our employees, have increasingly focused on, and are expected to continue to focus

on, our ESG practices. If our ESG practices fail to meet these stakeholders' expectations and standards, there could be a material adverse effect on our reputation, business and, ultimately, our stock price.

Our ESG report is made available on our website and describes our ESG goals and the progress we have made on the ESG issues deemed most important to our external and internal stakeholders, based on surveys, interviews and certain frameworks for corporate responsibility. Achieving our ESG goals requires long-term investments and broad, coordinated activity, and we may be required to incur additional costs or allocate additional resources towards monitoring, reporting and implementing our ESG practices. Further, we may fail to accurately assess our stakeholders' ESG priorities, as such priorities have evolved and will continue to evolve. While we have achieved most of our goals set in prior years, whether we can achieve our current and future ESG goals continues to be uncertain and remains subject to numerous risks, including evolving regulatory requirements and social expectations affecting ESG practices, our ability to recruit, develop and retain a diverse workforce, the availability of suppliers and collaboration partners that can meet our ESG goals, the effects of the organic growth of our business and potential acquisitions of other businesses on our ESG performance, and the availability and cost of technologies or resources, such as carbon credits, that support our goals. Any failure or perceived failure to meet our ESG program priorities could result in a material adverse effect on our reputation, business and stock price.

The effects of global climate change and related natural disasters could negatively affect our business and operations.

Many of our operations and facilities, including those essential to our manufacturing, R&D and distribution activities, are in locations that are subject to natural disasters, including droughts, fires, hurricanes, tropical storms, and/or floods. For example, in 2017 Hurricane Maria caused catastrophic damage to the U.S. territory of Puerto Rico, where we perform a substantial majority of our commercial manufacturing activities. Although our site was well-protected and suffered minimal damage, there can be no assurances that we would have similar results in the face of future natural disasters. The severity and frequency of weather-related natural disasters has been amplified, and is expected to continue to be amplified by, global climate change. Such natural disasters have caused, and in the future may cause, damage to and/or disrupt our operations, which may result in a material adverse effect on our product sales, business and results of operations. Our suppliers, vendors and business partners also face similar risks, and any disruption to their operations could have an adverse effect on our supply and manufacturing chain. Further, many of our key facilities are located on islands, including Puerto Rico, Singapore and Ireland, which rely on essential port facilities that may be vulnerable to climate change-related or other natural disasters. Although we have detailed business continuity plans in place and periodic assessments of our natural disaster risk, any natural disaster may also result in prolonged interruption to our critical operational and business activities, and we may be required to incur significant costs to remedy the effects of such natural disasters and fully resume operations, which may result in a material adverse effect on our product sales, business and results of operations. See *We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials* and *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

GENERAL RISK FACTORS

Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Our operations and performance have been, and may continue to be, affected by global economic conditions. The economic downturn resulting from the COVID-19 pandemic has precipitated a global recession which may be of an extended duration. Additionally, financial pressures may cause government or other third-party payers to more aggressively seek cost containment measures. See *Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.* As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships (including inflation) may also affect patients' ability to afford health care as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to reduced demand for our products, which could have a material adverse effect on our product sales, business and results of operations. The current inflationary environment related to increased aggregate demand and supply chain constraints have also increased our operating expenses and may continue to affect our operating expenses. Economic conditions may also

adversely affect the ability of our distributors, customers and suppliers to obtain the liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Although we monitor our distributors', customers' and suppliers' financial condition and their liquidity to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could have a material adverse effect on our product sales, business and results of operations. A significant worsening of global economic conditions could materially increase these risks we face.

We maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our consolidated balance sheets. The global spread of COVID-19 has also led to disruption and volatility in the global capital markets. We have certain assets, including equity investments, that are exposed to market fluctuations that could, in a sustained or recurrent series of market disruptions, result in impairments. The value of our investments may also be adversely affected by interest rate fluctuations, inflation, downgrades in credit ratings, illiquidity in the capital markets and other factors that may result in other-than-temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on sales of investments.

Our stock price is volatile.

Our stock price, like that of our peers in the biotechnology and pharmaceutical industries, is volatile. Our revenues and operating results may fluctuate from period to period for a number of reasons. Events such as a delay in product development, changes to our expectations or strategy or even a relatively small revenue shortfall may cause financial results for a period to be below our expectations or projections. As a result, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Announcements or discussions, including via social media channels, of possible restrictive actions by government or private payers that would negatively affect our business or industry if ultimately enacted or adopted may also cause our stock price to fluctuate, whether or not such restrictive actions ever actually occur. Similarly, actual or perceived safety issues with our products or similar products or unexpected clinical trial results can have an immediate and rapid effect on our stock price, whether or not our operating results are materially affected.

We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The capital and credit markets may experience extreme volatility and disruption, which may lead to uncertainty and liquidity issues for both borrowers and investors. For example, early in 2020, there were significant disruptions in the commercial paper market and several borrowers were unable to obtain funding at normal rates or maturities, which resulted in a significant increase in draws of corporate credit lines with banks. Similarly, the bond markets experienced extreme volatility in terms of interest rates and credit spreads, with several days without new issuances of corporate bonds. We expect to access the capital markets, from time to time, to supplement our existing funds and cash generated from operations in satisfying our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we strategically plan to pursue, including acquisitions and licensing activities. In the event of adverse capital and credit market conditions, we may be unable to obtain capital market financing on similar favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Changes in credit ratings issued by nationally recognized credit-rating agencies could adversely affect our ability to obtain capital market financing and the cost of such financing and have an adverse effect on the market price of our securities.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. **PROPERTIES**

As of December 31, 2021, we owned or leased approximately 160 properties. The locations and primary functions of significant properties are summarized in the following tables:

U.S. Location:	Manufacturing	Administrative	R&D	Sales & marketing	Warehouse	Distribution center
Thousand Oaks, CA*	✓	✓	✓	✓	✓	✓
San Francisco, CA			✓			
Louisville, KY					✓	✓
Cambridge, MA			✓			
Juncos, Puerto Rico	✓	✓			✓	✓
West Greenwich, RI	✓	✓			✓	
Tampa, FL		✓				
Other U.S. cities		✓		✓		

* Corporate headquarters

ROW Location:	Manufacturing	Administrative	R&D	Sales & marketing	Warehouse	Distribution center
Brazil	✓	✓		✓	✓	✓
Canada		✓	✓	✓		
China		✓		✓		
Denmark		✓	✓	✓		
Germany		✓	✓	✓		
Iceland		✓	✓			
Ireland	✓	✓		✓	✓	
Japan		✓		✓		
Netherlands	✓	✓		✓	✓	✓
Singapore	✓	✓		✓	✓	
Switzerland		✓		✓		
Turkey	✓	✓		✓	✓	✓
United Kingdom		✓	✓	✓		
Other countries		✓	✓	✓	✓	

Excluded from the information above are (i) undeveloped land and leased properties that have been abandoned and (ii) certain buildings we still own but that are no longer used in our business. There are no material encumbrances on our owned properties.

We believe our facilities are suitable for their intended uses and, in conjunction with our third-party contract manufacturing agreements, provide adequate capacity and are sufficient to meet our expected needs. See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

See Item 1. Business—Manufacturing, Distribution and Raw Materials.

Item 3. **LEGAL PROCEEDINGS**

Certain of the legal proceedings in which we are involved are discussed in Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements and are hereby incorporated by reference.

Item 4. **MINE SAFETY DISCLOSURES**

Not applicable.

PART II

Item 5. **MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Common stock

Our common stock trades on the NASDAQ Global Select Market under the symbol AMGN. As of February 11, 2022, there were approximately 5,069 holders of record of our common stock.

Performance graph

The following graph shows the value of an investment of $100 on December 31, 2016, in each of Amgen common stock, the Amex Biotech Index, the Amex Pharmaceutical Index and Standard & Poor's 500 Index. All values assume reinvestment of the pretax value of dividends and are calculated as of December 31 of each year. The historical stock price performance of the Company's common stock shown in the performance graph is not necessarily indicative of future stock price performance.

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	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021
Amgen (AMGN)	$100.00	$122.32	$140.76	$179.65	$176.05	$177.59
Amex Biotech (BTK)	$100.00	$137.81	$138.18	$166.41	$189.00	$182.34
Amex Pharmaceutical (DRG)	$100.00	$116.63	$125.31	$148.36	$161.31	$199.02
Standard & Poor's 500 (SPX)	$100.00	$121.89	$116.56	$153.26	$181.44	$233.47

The material in the above performance graph is not soliciting material, is not deemed filed with the SEC and is not incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made on, before or after the date of this filing and irrespective of any general incorporation language in such filing.

Stock repurchase program

During the three months and year ended December 31, 2021, we had one outstanding stock repurchase program, under which the repurchasing activity was as follows:

	Total number of shares purchased	Average price paid per share[1]	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program[2]
October 1 - October 31	1,874,976	$ 208.06	1,874,976	$ 6,960,277,756
November 1 - November 30	2,484,905	$ 208.35	2,484,905	$ 6,442,554,907
December 1 - December 31	2,559,300	$ 216.14	2,559,300	$10,889,377,513
	6,919,181	$ 211.15	6,919,181	
January 1 - December 31	21,730,283	$ 229.50	21,730,283	

(1) Average price paid per share includes related expenses.

(2) In October 2021 and December 2021, our Board of Directors increased the amount authorized under the stock repurchase program by an additional $4.5 billion and an additional $5.0 billion, respectively.

Dividends

For the years ended December 31, 2021 and 2020, we paid quarterly dividends. We expect to continue to pay quarterly dividends, although the amount and timing of any future dividends are subject to approval by our Board of Directors. Additional information required by this item is incorporated herein by reference to Part IV—Note 16, Stockholders' equity, to the Consolidated Financial Statements.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

Information about securities authorized for issuance under existing equity compensation plans is incorporated by reference from Item 12—Securities Authorized for Issuance Under Existing Equity Compensation Plans.

Item 6. **RESERVED**

Item 7. **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following MD&A is intended to assist the reader in understanding Amgen's business. MD&A is provided as a supplement to, and should be read in conjunction with, our consolidated financial statements and accompanying notes. Our results of operations discussed in MD&A are presented in conformity with GAAP. Amgen operates in one business segment: human therapeutics. Therefore, our results of operations are discussed on a consolidated basis.

Forward-looking statements

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. In addition, we, or others on our behalf, may make forward-looking statements in press releases, written statements or our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Such words as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume" and "continue" as well as variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and they involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in Part I, Item 1A. Risk Factors. We have based our forward-looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecasted by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, EPS, liquidity and capital resources, trends, planned dividends, stock repurchases, collaborations and effects of pandemics. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

Amgen is a biotechnology company committed to unlocking the potential of biology for patients suffering from serious illnesses. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Our principal products are ENBREL, Prolia, Otezla, XGEVA, Neulasta, Aranesp, Repatha, KYPROLIS and Nplate. We also market a number of other products, including MVASI, Vectibix, KANJINTI, EVENITY, EPOGEN, BLINCYTO, AMGEVITA, Aimovig, Parsabiv, NEUPOGEN, LUMAKRAS/LUMYKRAS, Sensipar/Mimpara and TEZSPIRE. For additional information about our products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products.

Our strategy includes integrated activities intended to maintain and strengthen our competitive position in the industry. We focus on six commercial areas: inflammation, oncology/hematology, bone health, CV disease, nephrology and neuroscience. And we conduct discovery research primarily in three therapeutic areas: inflammation, oncology/hematology and general medicine. In 2021, we advanced our innovative pipeline, launched new products, completed several strategic transactions to augment our pipeline and research capabilities, and continued providing uninterrupted supplies of our medicines globally through the second year of the COVID-19 pandemic. We accomplished these objectives while maintaining a strategic and disciplined approach to capital allocation and while advancing our ESG efforts.

In 2021, we continued to advance our pipeline, including achieving key regulatory approvals for LUMAKRAS and TEZSPIRE. Our external business development activities for 2021 included: (i) acquiring Five Prime, including a later-stage gastric cancer bemarituzumab program; (ii) entering into a license agreement with KKC to develop a later-stage molecule for atopic dermatitis and other diseases; and (iii) acquiring Teneobio for its proprietary technologies and oncology programs in development. We also continued to advance our biosimilar program with the launch of RIABNI in the United States and introduced our other biosimilars into new markets. Our biosimilars are expected to continue launching in new markets throughout 2022.

During 2021, while meeting the challenges of a global pandemic and facing increased competition from biosimilars and generics, total product sales were relatively flat as volume growth was offset by lower net selling prices. Product sales decreased 4% in the United States, driven by lower net selling prices, partially offset by volume growth, and increased 12% ROW, driven by volume growth, partially offset by lower net selling prices. Total operating expenses increased 13%, driven by IPR&D expense from the Five Prime acquisition and the upfront payment associated with the KKC licensing agreement.

Cash flows from operating activities totaled $9.3 billion, which supported investment in our business while returning capital to shareholders through the payment of cash dividends and stock repurchases. For 2021, we increased our quarterly cash dividend by 10% to $1.76 per share of common stock. In December 2021, we declared a cash dividend of $1.94 per share of common stock for the first quarter of 2022, an increase of 10% for this period, to be paid in March 2022. We also repurchased 21.7 million shares of our common stock during 2021 at an aggregate cost of $5.0 billion. In 2021, we issued $4.9 billion and repaid $4.2 billion of debt that was coming due in 2022.

Amgen's approach to, and investment in, human capital resource management is directed at attracting, motivating, developing and retaining talent to tackle the challenges of running an enterprise focused on the discovery, development and commercialization of innovative medicines. Our compensation, benefits and development programs are designed to encourage performance, promote accountability and adherence to Company values, and align with the interests of the Company's shareholders. Further, we believe that a diverse and inclusive culture fosters innovation, which supports our ability to serve patients. We are engaging in activities and setting goals to improve our focus on diversity, inclusion and belonging. For further information on these and other efforts, see Part I, Item 1. Business—Human Capital Resources.

We have a long-standing ambition to be environmentally responsible, and we regularly set targets to challenge ourselves to deliver further improvements. In 2020, we met or exceeded our environmental sustainability targets set out in 2013 that called for reducing fleet carbon output by up to 20%, facility carbon output by 10%, water consumption by 10% and waste disposal by 35%.[2] We achieved our 2020 targets while growing revenues, increasing production capacity and expanding to approximately 100 countries over the same 2013–20 period. To continue on our path to greater environmental sustainability, in January 2021 we announced a new set of long-term environmental

targets to achieve by 2027, including achieving carbon neutrality, reducing water consumption by 40% and reducing waste disposed by 75%.[2, 3]

[2] Represents reductions against established baselines, taking into account only verified reduction projects, and does not take into account changes associated with contraction or expansion of the Company.
[3] Carbon neutrality goal refers to Scope 1 and 2.

Our long-term success depends, to a great extent, on our ability to continue to discover, develop and commercialize innovative products and acquire or collaborate on therapies currently in development by other companies. We must develop new products to achieve revenue growth and to offset revenue losses from when products lose their exclusivity or when competing products are launched. Certain of our products face increasing pressure from competition, including biosimilars and generics. For additional information, including information on the expirations of patents for various products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents, and Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We devote considerable resources to R&D activities, but successful product development in the biotechnology industry is highly uncertain. We also face increasing regulatory scrutiny of safety and efficacy both before and after products launch.

Rising healthcare costs and uncertain economic conditions continue to pose challenges to our business, including increasing pressure by third-party payers, such as governments and private payers, to reduce healthcare expenditures. As a result of public and private healthcare-provider focus, the industry continues to be subject to cost containment measures and significant pricing pressures, including net price declines. Finally, wholesale and end-user buying patterns can affect our product sales. These buying patterns can cause fluctuations in quarterly product sales but have generally not been significant to date when comparing full-year product performance to the prior year. See Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products, and Part I, Item 1A. Risk Factors for further discussion of certain factors that could impact our future product sales.

COVID-19 pandemic

Since the onset of the pandemic in 2020, we have been closely monitoring the pandemic's effects on our global operations. We continue to take appropriate steps to minimize risks to our employees, a significant number of whom have continued to work virtually. Employee access to company facilities has been in accordance with applicable government health and safety protocols and guidance issued in response to the COVID-19 pandemic. To date, our remote working arrangements have not significantly affected our ability to maintain critical business operations, and we have not experienced disruptions to or shortages of our supply of medicines.

Since the beginning of the COVID-19 pandemic, we have seen changes in demand for some of our products driven by changes in the frequency of patient visits to doctors' offices that has impacted the provision of treatments to existing patients and reduced diagnoses in new patients. During 2021, there was gradual recovery in both patient visits and diagnoses that approached pre-COVID-19 levels early in the fourth quarter. However late in 2021, the Omicron variant began to impact the healthcare sector and as a result we expect ongoing variability in demand patterns in the first half of 2022. The cumulative decrease in diagnoses over the course of the pandemic has suppressed the volume of new patients starting treatment, which we expect to continue to impact our business. We will continue to closely monitor the effects of emerging COVID-19 variants on patient behavior and access to care.

Since early 2021, global vaccination efforts have been under way to control the pandemic. However, uncertainty remains as to the length of time required for vaccination of a meaningful portion of the population and as to the efficacy of such vaccinations with regard to the trajectory of the pandemic. Challenges to vaccination efforts, new variants and other causes of virus spread may require governments to issue additional restrictions and/or order shutdowns in various geographies. As a result, we expect to see continued volatility for at least the duration of the pandemic as governments respond to current local conditions.

With respect to our drug development activities, we are continuously monitoring COVID-19 infection rates, including changes from new variants, and working to mitigate effects on future study enrollment in our clinical trials and evaluating the impacts in all countries where our clinical trials occur. We remain focused on supporting our active clinical sites in their provision of care to patients and in our provision of investigational drug supply.

Despite the ongoing pandemic and business impacts noted above, we believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital, capital expenditures and debt service requirements as well as to engage in capital-return and other business initiatives that we plan to pursue. For a discussion of the risks the COVID-19 pandemic presents to our results, see Risk Factors in Part I, Item 1A. Risk Factors of this Form 10-K.

Selected Financial Information

The following is an overview of our results of operations (in millions, except percentages and per-share data):

	Year ended December 31, 2021	Change	Year ended December 31, 2020
Product sales:			
U.S.	$ 17,286	(4)%	$ 17,985
ROW	7,011	12 %	6,255
Total product sales	24,297	— %	24,240
Other revenues	1,682	42 %	1,184
Total revenues	$ 25,979	2 %	$ 25,424
Operating expenses	$ 18,340	13 %	$ 16,285
Operating income	$ 7,639	(16)%	$ 9,139
Net income	$ 5,893	(19)%	$ 7,264
Diluted EPS	$ 10.28	(16)%	$ 12.31
Diluted shares	573	(3)%	590

In the following discussion of changes in product sales, any reference to unit demand growth or decline refers to changes in the purchases of our products by healthcare providers (such as physicians or their clinics), dialysis centers, hospitals and pharmacies. In addition, any reference to increases or decreases in inventory refers to changes in inventory held by wholesaler customers and end users (such as pharmacies).

Total product sales were relatively flat for 2021, as volume growth was offset by declines in net selling prices. For 2022, we expect that net selling prices will continue to decline at a portfolio level driven by increased competition. Further, the first quarter of a year historically represents the lowest product sales quarter for the year, in part due to plan changes, insurance reverifications and higher co-pay expenses as U.S. patients work through deductibles, particularly for products acquired through pharmacy benefit programs.

Throughout the pandemic, we experienced changes in demand for some of our products. The pandemic has interrupted many physician–patient interactions, which has led to delays in diagnoses and treatments, with varying degrees of impact across our portfolio. In general, declines in the sales of our products that were impacted by the dynamics of the pandemic were most significant in the early months of the pandemic with product demand beginning to show some recovery in late 2020. During 2021, we observed gradual recovery from the COVID-19 pandemic, with patient visits and diagnosis rates that approached pre-pandemic levels early in the fourth quarter. However, late in the year, the Omicron variant began to impact the healthcare sector and as a result, we have seen some shift back to virtual engagement by our field staff and variability in demand patterns. The cumulative decrease in diagnoses over the course of the pandemic has suppressed the volume of new patients starting treatment, which we expect to continue to impact our business. Given the unpredictable nature of the pandemic, we expect there could be ongoing intermittent disruptions in physician–patient interactions, and as a result, we continue to expect quarter-to-quarter variability. In addition, other changes in the healthcare ecosystem have the potential to introduce variability into product sales trends. For example, changes in U.S. employment have led to changes to the insured population. Growth in numbers of Medicaid enrollees and uninsured individuals may have a negative impact on product demand and sales. Overall, uncertainty remains around the timing and magnitude of our sales during the COVID-19 pandemic. See Risk Factors in Part I, Item 1A. of this Form 10-K.

Other revenues increased for 2021, primarily driven by the sale of COVID-19 antibody material resulting from our manufacturing collaboration.

Operating expenses increased for 2021, driven by IPR&D expense related to the bemarituzumab program acquired as part of the Five Prime acquisition and by the upfront payment associated with the KKC licensing agreement.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is partially offset by corresponding increases or decreases in our international operating expenses and our related

foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material in 2021, 2020 or 2019.

Results of Operations

Product sales

Worldwide product sales were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
ENBREL	$ 4,465	(11)%	$ 4,996	(4)%	$ 5,226
Prolia	3,248	18 %	2,763	3 %	2,672
Otezla	2,249	2 %	2,195	*	178
XGEVA	2,018	6 %	1,899	(2)%	1,935
Neulasta	1,734	(24)%	2,293	(29)%	3,221
Aranesp	1,480	(6)%	1,568	(9)%	1,729
Repatha	1,117	26 %	887	34 %	661
KYPROLIS	1,108	4 %	1,065	2 %	1,044
Nplate	1,027	21 %	850	7 %	795
Other products	5,851	2 %	5,724	21 %	4,743
Total product sales	$ 24,297	— %	$ 24,240	9 %	$ 22,204
Total U.S.	$ 17,286	(4)%	$ 17,985	9 %	$ 16,531
Total ROW	7,011	12 %	6,255	10 %	5,673
Total product sales	$ 24,297	— %	$ 24,240	9 %	$ 22,204

* Change in excess of 100%.

Future sales of our products will depend in part on the factors discussed in the Overview, Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition, in Part I, Item 1A. Risk Factors, and any additional factors discussed in the individual product sections below. In addition, for a list of our products' significant competitors, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition.

ENBREL

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
ENBREL — U.S.	$ 4,352	(10)%	$ 4,855	(4)%	$ 5,050
ENBREL — Canada	113	(20)%	141	(20)%	176
Total ENBREL	$ 4,465	(11)%	$ 4,996	(4)%	$ 5,226

The decrease in ENBREL sales for 2021 was driven by lower net selling price, unit demand and unfavorable changes in inventory. For 2022, we expect ENBREL to follow the historical pattern of lower sales in the first quarter relative to subsequent quarters due to the impact of benefit plan changes, insurance reverification and increased co-pay expenses as U.S. patients work through deductibles. In addition, for 2022, we expect net selling price to decline.

The decrease in ENBREL sales for 2020 was driven by lower unit demand and net selling price, partially offset by favorable changes to estimated sales deductions and inventory.

Prolia

Total Prolia sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
Prolia — U.S.	$ 2,150	17 %	$ 1,830	3 %	$ 1,772
Prolia — ROW	1,098	18 %	933	4 %	900
Total Prolia	$ 3,248	18 %	$ 2,763	3 %	$ 2,672

The increase in global Prolia sales for 2021 was primarily driven by higher unit demand.

The increase in global Prolia sales for 2020 was driven by higher unit demand and net selling price.

Otezla

Total Otezla sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
Otezla — U.S.	$ 1,804	1 %	$ 1,790	*	$ 139
Otezla — ROW	445	10 %	405	*	39
Total Otezla	$ 2,249	2 %	$ 2,195	*	$ 178

* Change in excess of 100%.

The increase in global Otezla sales for 2021 was driven by higher unit demand, partially offset by lower net selling price and unfavorable changes to inventory. For 2022, we expect Otezla to follow the historical pattern of lower sales in the first quarter relative to subsequent quarters due to the impact of benefit plan changes, insurance reverification and increased co-pay expenses as U.S. patients work through deductibles.

Otezla was acquired on November 21, 2019, and generated $2.2 billion and $178 million in global sales for the years ended December 31, 2020 and 2019, respectively.

For a discussion of ongoing litigation related to Otezla, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

XGEVA

Total XGEVA sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
XGEVA — U.S.	$ 1,434	2 %	$ 1,405	(4)%	$ 1,457
XGEVA — ROW	584	18 %	494	3 %	478
Total XGEVA	$ 2,018	6 %	$ 1,899	(2)%	$ 1,935

The increase in global XGEVA sales for 2021 was primarily driven by higher unit demand, partially offset by lower net selling price.

The decrease in global XGEVA sales for 2020 was driven by lower unit demand as a result of the COVID-19 pandemic.

Neulasta

Total Neulasta sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
Neulasta — U.S.	$ 1,514	(24)%	$ 2,001	(29)%	$ 2,814
Neulasta — ROW	220	(25)%	292	(28)%	407
Total Neulasta	$ 1,734	(24)%	$ 2,293	(29)%	$ 3,221

The decreases in global Neulasta sales for 2021 and 2020 was primarily driven by lower net selling price and unit demand. Increased competition as a result of biosimilar versions of Neulasta has had and will continue to have a significant adverse impact on brand sales, including accelerating net price erosion and lower unit demand. We also expect other biosimilar versions, including biosimilars that will use an on-body injector that would compete with our Onpro injector, to be approved in the future.

For a discussion of ongoing patent litigations related to biosimilars, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Aranesp

Total Aranesp sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
Aranesp — U.S.	$ 537	(15)%	$ 629	(17)%	$ 758
Aranesp — ROW	943	— %	939	(3)%	971
Total Aranesp	$ 1,480	(6)%	$ 1,568	(9)%	$ 1,729

The decrease in global Aranesp sales for 2021 was primarily driven by lower net selling price due to competition.

The decrease in global Aranesp sales for 2020 was driven by declines in net selling price and unit demand.

Aranesp continues to face competition from a long-acting ESA and from a biosimilar version of EPOGEN, which will continue to impact sales in the future.

Repatha

Total Repatha sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
Repatha — U.S.	$ 557	21 %	$ 459	22 %	$ 376
Repatha — ROW	560	31 %	428	50 %	285
Total Repatha	$ 1,117	26 %	$ 887	34 %	$ 661

The increases in global Repatha sales for 2021 and 2020 was driven by higher unit demand, partially offset by lower net selling price. Contracting changes to improve Medicare Part D patient access resulted in the decrease to net selling price.

For a discussion of ongoing litigation related to Repatha, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

KYPROLIS

Total KYPROLIS sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
KYPROLIS — U.S.	$ 736	4 %	$ 710	9 %	$ 654
KYPROLIS — ROW	372	5 %	355	(9)%	390
Total KYPROLIS	$ 1,108	4 %	$ 1,065	2 %	$ 1,044

The increase in global KYPROLIS sales for 2021 was primarily driven by higher unit demand.

The increase in global KYPROLIS sales for 2020 was primarily driven by an increase in net selling price and favorable changes in inventory, partially offset by lower unit demand.

The FDA has reported that it has granted tentative or final approval of ANDAs for generic carfilzomib products filed by a number of companies. The date of approval of those ANDAs for generic carfilzomib products is governed by the Hatch–Waxman Act and any applicable settlement agreements between us and certain companies that seek to develop generic carfilzomib products.

Nplate

Total Nplate sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
Nplate — U.S.	$ 566	17 %	$ 485	1 %	$ 480
Nplate — ROW	461	26 %	365	16 %	315
Total Nplate	$ 1,027	21 %	$ 850	7 %	$ 795

The increases in global Nplate sales for 2021 and 2020 was primarily driven by higher unit demand.

Other products

Other product sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
MVASI — U.S.	$ 826	26 %	$ 656	*	$ 121
MVASI — ROW	340	*	142	*	6
Vectibix — U.S.	347	1 %	342	8 %	316
Vectibix — ROW	526	12 %	469	10 %	428
KANJINTI — U.S.	479	1 %	475	*	118
KANJINTI — ROW	93	1 %	92	(15)%	108
EVENITY — U.S.	331	73 %	191	*	42
EVENITY — ROW	199	25 %	159	8 %	147
EPOGEN — U.S.	521	(13)%	598	(31)%	867
BLINCYTO — U.S.	278	20 %	231	31 %	176
BLINCYTO — ROW	194	31 %	148	9 %	136
AMGEVITA — ROW	439	33 %	331	54 %	215
Aimovig — U.S.	313	(17)%	378	24 %	306
Aimovig — ROW	4	N/A	—	N/A	—
Parsabiv — U.S.	150	(75)%	605	10 %	550
Parsabiv— ROW	130	17 %	111	39 %	80
NEUPOGEN — U.S.	101	(30)%	144	(19)%	178
NEUPOGEN — ROW	67	(17)%	81	(6)%	86
LUMAKRAS — U.S.	82	N/A	—	N/A	—
LUMYKRAS — ROW	8	N/A	—	N/A	—
Sensipar — U.S.	6	(93)%	92	(63)%	252
Sensipar/Mimpara — ROW	78	(60)%	196	(34)%	299
Other — U.S.	202	85 %	109	4 %	105
Other — ROW	137	(21)%	174	(16)%	207
Total other product sales	$ 5,851	2 %	$ 5,724	21 %	$ 4,743
Total U.S. — other products	$ 3,636	(5)%	$ 3,821	26 %	$ 3,031
Total ROW — other products	2,215	16 %	1,903	11 %	1,712
Total other product sales	$ 5,851	2 %	$ 5,724	21 %	$ 4,743

* Change in excess of 100%.

N/A = not applicable

Operating expenses

Operating expenses were as follows (dollar amounts in millions):

	Year ended December 31, 2021	Change	Year ended December 31, 2020	Change	Year ended December 31, 2019
Cost of sales	$ 6,454	5 %	$ 6,159	41 %	$ 4,356
% of product sales	26.6 %		25.4 %		19.6 %
% of total revenues	24.8 %		24.2 %		18.6 %
Research and development	$ 4,819	15 %	$ 4,207	2 %	$ 4,116
% of product sales	19.8 %		17.4 %		18.5 %
% of total revenues	18.5 %		16.5 %		17.6 %
Acquired in-process research and development	$ 1,505	N/A	$ —	N/A	$ —
% of product sales	6.2 %		— %		— %
% of total revenues	5.8 %		— %		— %
Selling, general and administrative	$ 5,368	(6)%	$ 5,730	11 %	$ 5,150
% of product sales	22.1 %		23.6 %		23.2 %
% of total revenues	20.7 %		22.5 %		22.0 %
Other	$ 194	3 %	$ 189	*	$ 66
Total operating expenses	$ 18,340	13 %	$ 16,285	19 %	$ 13,688

* Change in excess of 100%

N/A = not applicable

Cost of sales

Cost of sales increased to 24.8% of total revenues for 2021, driven by unfavorable product mix and higher profit share and royalties, partially offset by lower amortization expense from acquisition-related assets and lower manufacturing costs.

Cost of sales increased to 24.2% of total revenues for 2020, primarily driven by the amortization of expenses related to our acquisition of Otezla and by higher royalty expenses and profit share, partially offset by lower manufacturing costs.

Research and development

The Company groups all of its R&D activities and related expenditures into three categories: (i) research and early pipeline, (ii) later-stage clinical programs and (iii) marketed products. These categories are described below:

Category	Description
Research and early pipeline	R&D expenses incurred in activities substantially in support of early research through the completion of phase 1 clinical trials, including drug discovery, toxicology, pharmacokinetics and drug metabolism, and process development
Later-stage clinical programs	R&D expenses incurred in or related to phase 2 and phase 3 clinical programs intended to result in registration of a new product or a new indication for an existing product primarily in the United States or the EU
Marketed products	R&D expenses incurred in support of the Company's marketed products that are authorized to be sold primarily in the United States or the EU. Includes clinical trials designed to gather information on product safety (certain of which may be required by regulatory authorities) and their product characteristics after regulatory approval has been obtained, as well as the costs of obtaining regulatory approval of a product in a new market after approval in either the United States or the EU has been obtained

R&D expense by category was as follows (in millions):

	Years ended December 31,		
	2021	2020	2019
Research and early pipeline	$ 1,670	$ 1,405	$ 1,649
Later-stage clinical programs	1,726	1,365	1,062
Marketed products	1,423	1,437	1,405
Total R&D expense	$ 4,819	$ 4,207	$ 4,116

The increase in R&D expense for 2021 was driven by a licensing-related expense from our collaboration with KKC included in later-stage clinical programs and higher spend in research and early pipeline, including other business development activities.

The increase in R&D expense for 2020 was driven by higher spend for later-stage clinical programs, including LUMAKRAS, biosimilar programs and Otezla, and higher spend for Otezla included in marketed-product support. These increases were partially offset by recoveries from our collaboration with BeiGene that reduced expenses in later-stage clinical programs and in research and early pipeline, and lower spend in certain oncology programs included in research and early pipeline.

Acquired in-process research and development

Acquired IPR&D expense for 2021 was related to the bemarituzumab program acquired as part of the Five Prime acquisition.

Selling, general and administrative

The decrease in SG&A expense for 2021 was primarily driven by lower spend for marketed products and lower general and administrative expenses.

The increase in SG&A expense for 2020 was driven by investments in certain marketed products, primarily Otezla, and preparation for product launches, partially offset by a reduction in conference-related expenses due to the impact of COVID-19.

Other

Other operating expenses for 2021 primarily consisted of expenses related to cost-savings initiatives and a legal judgment.

Other operating expenses for 2020 primarily consisted of legal settlement expenses.

Other operating expenses for 2019 primarily consisted of expenses related to cost-savings initiatives.

Nonoperating expenses/income and income taxes

Nonoperating expenses/income and income taxes were as follows (dollar amounts in millions):

	Years ended December 31,		
	2021	2020	2019
Interest expense, net	$ (1,197)	$ (1,262)	$ (1,289)
Other income, net	$ 259	$ 256	$ 753
Provision for income taxes	$ 808	$ 869	$ 1,296
Effective tax rate	12.1 %	10.7 %	14.2 %

Interest expense, net

The decrease in Interest expense, net, for 2021 was primarily due to net higher costs associated with the early retirement of debt in 2020 and lower LIBOR rates in 2021 on debt for which we effectively pay a variable rate of interest through the use of interest rate swaps, partially offset by higher overall debt outstanding.

The decrease in Interest expense, net, for 2020 was primarily due to lower LIBOR rates on debt for which we effectively pay a variable rate of interest, partially offset by net costs associated with the early retirement of debt.

Other income, net

The increase in Other income, net, for 2021 was primarily due to lower losses incurred in connection with our BeiGene investment compared with 2020, partially offset by lower income on our interest-bearing investments in 2021 and other nonrecurring gains recognized in 2020.

The decrease in Other income, net, for 2020 was primarily due to reduced interest income as a result of lower average cash balances and a decline in interest yields and losses incurred in connection with our BeiGene investment, partially offset by gains recognized on our investments in publicly traded equity securities and limited partnerships. See Part IV—Note 9, Investments, to the Consolidated Financial Statements.

Income taxes

The increase in our effective tax rate for 2021 compared with 2020 was primarily driven by the non-deductible IPR&D expense arising from the acquisition of Five Prime, partially offset by earnings mix and adjustments to prior-year tax liabilities.

The decrease in our effective tax rate for 2020 compared with 2019 was primarily driven by favorable items, including audit settlements, adjustments to prior-year tax liabilities, lower interest expense on uncertain tax positions and amortization related to the Otezla acquisition, partially offset by changes in valuation allowance.

The Administration proposed and Congress is considering significant changes to existing tax law. These changes, if enacted, could substantially increase taxes we pay to the U.S. government. Further, the OECD recently reached agreement to align countries on a minimum corporate tax rate and an expansion of the taxing rights of market countries. If enacted, this agreement could result in tax increases in both the United States and foreign jurisdictions. The U.S. Treasury recently released final foreign tax credit regulations that eliminate U.S. creditability of the Puerto Rico Excise Tax beginning in 2023, which will increase our U.S. tax liability. The U.S. territory of Puerto Rico is considering changes to its tax system that may minimize or eliminate this impact, but the outcome of such potential changes is uncertain. Changes to existing tax law in the United States, the U.S. territory of Puerto Rico, or other jurisdictions, including the potential changes discussed above, could result in tax increases where we do business and could have a material adverse effect on the results of our operations.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010, 2011 and 2012, proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS appeals office but were unable to reach resolution. In July 2021, we filed a petition in the U.S. Tax Court to contest two duplicate Notices for 2010, 2011 and 2012 that we received in May and July 2021 which seek to increase our U.S. taxable income. The Notices seek to increase our U.S. taxable income by an amount that would result in additional federal tax of approximately $3.6 billion plus interest. Any additional tax that could be imposed would be reduced by up to approximately $900 million of repatriation tax previously accrued on our foreign earnings. We firmly believe that the IRS's positions set forth in the Notices are without merit, and we are contesting the Notices through the judicial process.

In 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015, also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS appeals office. We were unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a statutory notice of deficiency for these years as well. We expect to contest any such notice related to 2013–15 through the judicial process. We are also currently under examination by the IRS for the years 2016, 2017 and 2018 and by a number of state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and the uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our consolidated financial statements.

See Part I, Item 1A. Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability;* Part II, Item 7. MD&A—Critical Accounting Policies and Estimates—Income taxes; and Part IV—Note 6, Income taxes, to the Consolidated Financial Statements for further discussion.

Financial Condition, Liquidity and Capital Resources

Selected financial data was as follows (in millions):

	December 31,	
	2021	2020
Cash, cash equivalents and marketable securities	$ 8,037	$ 10,647
Total assets	$ 61,165	$ 62,948
Current portion of long-term debt	$ 87	$ 91
Long-term debt	$ 33,222	$ 32,895
Stockholders' equity	$ 6,700	$ 9,409

Cash, cash equivalents and marketable securities

Our balance of cash, cash equivalents and marketable securities was $8.0 billion at December 31, 2021. The primary objective of our investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

Capital allocation

Consistent with the objective to optimize our capital structure, we deploy our accumulated cash balances in a strategic manner and consider a number of alternatives, including strategic transactions (including those that expand our portfolio of products in areas of therapeutic interest), repayment of debt, payment of dividends and stock repurchases.

We intend to continue investing in our business while returning capital to stockholders through the payment of cash dividends and stock repurchases, thereby reflecting our confidence in the future cash flows of our business and our desire to optimize our cost of capital. The timing and amount of future dividends and stock repurchases will vary based on a number of factors, including future capital requirements for strategic transactions, availability of financing on acceptable terms, debt service requirements, our credit rating, changes to applicable tax laws or corporate laws, changes to our business model and periodic determination by our Board of Directors that cash dividends and/or stock repurchases are in the best interests of stockholders and are in compliance with applicable laws and the Company's agreements. In addition, the timing and amount of stock repurchases may also be affected by our overall level of cash, stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include block purchases, tender offers, accelerated share repurchases and market transactions.

The Board of Directors declared quarterly cash dividends of $1.76, $1.60 and $1.45 per share of common stock paid in 2021, 2020 and 2019, respectively, an increase of 10% over the prior year in both 2021 and 2020. In December 2021, the Board of Directors declared a cash dividend of $1.94 per share of common stock for the first quarter of 2022, an increase of 10% for this period, to be paid in March 2022.

We also returned capital to stockholders through our stock repurchase program. During 2021, we repurchased and had cash settlements of $5.0 billion of common stock. In 2020, we repurchased and had cash settlements of $3.5 billion of common stock. In 2019, we repurchased $7.6 billion of common stock and had cash settlements of $7.7 billion. In March 2021, October 2021 and December 2021, the Board of Directors increased the amount authorized under our stock repurchase program by $3.4 billion, $4.5 billion and $5.0 billion, respectively. As of December 31, 2021, $10.9 billion remained available under the stock repurchase program.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of December 31, 2021 and 2020. Our accumulated deficit is not anticipated to affect our future ability to operate, repurchase stock, pay dividends or repay our debt given our expected continued profitability and strong financial position.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital, capital expenditure and debt service requirements, our plans to pay dividends and repurchase stock, and other business initiatives we plan to strategically pursue, including

acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or syndicated credit facilities, and access to other domestic and foreign debt markets and equity markets. See Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business*.

Financing arrangements

To help meet our liquidity requirements, we have entered into various financing arrangements. The noncurrent portions of our long-term borrowings as of December 31, 2021 and 2020, were $33.2 billion and $32.9 billion, respectively. The carrying values of our long-term borrowings are net of fair value adjustments for interest rate swaps and unamortized discounts, premiums and offering costs. As of December 31, 2021, S&P, Moody's and Fitch assigned credit ratings to our outstanding senior notes of A– with a stable outlook, Baa1 with a stable outlook and BBB+ with a stable outlook, respectively, which are considered investment grade. Unfavorable changes to these ratings may have an adverse impact on future financings.

During 2021 and 2020, we issued debt with aggregate principal amounts of $5.0 billion and $9.0 billion, respectively. During 2019, we did not issue any debt or debt securities. During 2021, 2020 and 2019, we repaid/redeemed debt of $4.2 billion, $6.5 billion and $4.5 billion, respectively. In addition, during 2020, we exchanged $0.7 billion of certain of our outstanding note issuances with $0.9 billion of newly issued notes with a lower interest rate and later maturity date.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating, LIBOR-based coupon over the lives of the respective notes. These interest rate swap contracts qualify and are designated as fair value hedges. As of December 31, 2021 and 2020, we had interest rate swap contracts with aggregate notional amounts of $6.7 billion and $5.9 billion, respectively.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts, which effectively convert the interest payments and principal repayment of the respective notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts qualify and are designated as cash flow hedges. As of both December 31, 2021 and 2020, we had cross-currency swap contracts with aggregate notional amounts of $3.4 billion and $4.8 billion, respectively.

As of December 31, 2021, we had a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. During 2021, 2020 and 2019, we did not issue any commercial paper. No commercial paper was outstanding as of December 31, 2021 and 2020.

In 2019, we amended and restated our $2.5 billion syndicated, unsecured, revolving credit agreement, which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $750 million with the agreement of the banks. Each bank that is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest for any amounts borrowed under this facility, based on our current credit rating, at (i) LIBOR plus 1% or (ii) the highest of (A) the syndication agent bank base commercial lending rate, (B) the overnight federal funds rate plus 0.50% or (C) one-month LIBOR plus 1%. The agreement contains provisions related to the determination of successor rates to address the possible phaseout or unavailability of designated reference rates. As of December 31, 2021 and 2020, no amounts were outstanding under this facility.

It is anticipated that the U.S. dollar LIBOR rate will be phased out and replaced by 2023. The Alternative Reference Rates Committee, a group of private-market participants convened by the Federal Reserve Board and the Federal Reserve Bank of New York to help ensure a successful transition from U.S. dollar LIBOR to a more robust reference rate, recommends SOFR as the U.S. dollar LIBOR alternative. As such, we expect SOFR to become widely adopted by market participants. We do not expect this change to have a material impact on our financial statements. See Part I, Item 1A. Risk Factors—*Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.*

In February 2020, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2023.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant that requires us to maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2021.

These financing arrangements are more fully discussed in Part IV—Note 15, Financing arrangements, and Note 18, Derivative instruments, to the Consolidated Financial Statements.

Cash flows

Our summarized cash flow activity was as follows (in millions):

	Years ended December 31,		
	2021	2020	2019
Net cash provided by operating activities	$ 9,261	$ 10,497	$ 9,150
Net cash provided by (used in) investing activities	$ 733	$ (5,401)	$ 5,709
Net cash used in financing activities	$ (8,271)	$ (4,867)	$ (15,767)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities decreased during 2021 primarily due to the monetization of interest rate swaps that occurred in 2020 and the timing of payments for sales incentives and discounts. Cash provided by operating activities increased during 2020 primarily due to higher Net income after adding back the noncash amortization related to the acquisition of Otezla, the monetization of interest rate swap contracts and working-capital adjustments.

Investing

Cash provided by investing activities during 2021 was primarily due to net cash inflows related to marketable securities of $4.3 billion, partially offset by cash used in the acquisitions of Teneobio and Five Prime of $2.5 billion. Cash used in investing activities during 2020 was primarily due to our $3.2 billion of purchases of equity method investments, primarily BeiGene, and net cash outflows related to marketable securities of $1.5 billion. Cash provided by investing activities during 2019 was primarily due to net cash inflows related to marketable securities of $20.0 billion which occurred primarily to fund our acquisition of Otezla and investment in BeiGene. Capital expenditures were $880 million, $608 million and $618 million in 2021, 2020 and 2019, respectively. We currently estimate 2022 spending on capital projects to be approximately $950 million. A majority of the increase in expenditures relates to expansion of manufacturing capacity to enable supply of products and product candidates.

Financing

Cash used in financing activities during 2021 was primarily due to payments to repurchase our common stock of $5.0 billion and the payment of dividends of $4.0 billion, partially offset by proceeds from the issuance of debt, net of repayments of $0.8 billion. Cash used in financing activities during 2020 was primarily due to the payment of dividends of $3.8 billion and payments to repurchase our common stock of $3.5 billion, partially offset by proceeds from issuance of debt, net of repayments of $2.5 billion. Cash used in financing activities during 2019 was primarily due to payments to repurchase our common stock of $7.7 billion, repayment of debt of $4.5 billion and payments of dividends of $3.5 billion.

See Part IV—Note 9, Investments; Note 15, Financing arrangements; and Note 16, Stockholders' equity, to the Consolidated Financial Statements.

Capital requirements

We have material cash requirements to pay third parties under various contractual obligations discussed below.

We are obligated to pay interest and repay principal under our various financing arrangements, including amounts under interest rate swap and cross-currency swap contracts related to certain of our long-term debt obligations. For information on scheduled debt maturities and payments under derivative contracts associated with our long-term debt obligations, see Part IV—Note 15, Financing arrangements, and Note 18, Derivative instruments, to the Consolidated Financial Statements.

We are obligated to make payments for operating leases, including rental commitments on abandoned leases and leases that have not yet commenced. For information on these obligations, see Part IV—Note 13, Leases, to the Consolidated Financial Statements.

Under the 2017 Tax Act, we elected to pay in eight annual installments the repatriation tax related primarily to prior indefinitely invested earnings of our foreign operations. For information on the remaining scheduled

repatriation tax installments, see Part IV—Note 19, Contingencies and commitments—Commitments—U.S. Repatriation tax, to the Consolidated Financial Statements.

We have purchase obligations of $3.2 billion primarily related to (i) R&D commitments (including those related to clinical trials) for new and existing products, (ii) capital expenditures and (iii) open purchase orders for the acquisition of goods and services in the ordinary course of business. Most of these obligations are expected to be paid within one year, and payment of certain of these amounts may be reduced based on certain future events.

In addition to the purchase obligations noted above, we are contractually obligated to pay additional amounts that in the aggregate are significant, upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties, including contingent consideration incurred in the acquisitions of Teneobio and K-A. These payments are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring, and any resulting cash requirements are managed through our operational budgeting processes. Except with respect to the fair value of the contingent consideration of approximately $0.3 billion, these obligations are not recorded on our Consolidated Balance Sheets. As of December 31, 2021, the maximum amount that may be payable in the future for agreements we have entered into with third parties is $7.4 billion, including $1.6 billion of contingent consideration payments in connection with our Teneobio acquisition.

We have recorded liabilities for UTBs that, because of their nature, have a high degree of uncertainty regarding the timing of future cash payment and other events that extinguish these liabilities. See Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. Our significant accounting policies are included in Part IV—Note 1, Summary of significant accounting policies. The following are considered critical to our consolidated financial statements because they require the most difficult, subjective or complex judgments, often because of the need to make estimates about matters that are inherently uncertain.

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate. Accruals are also adjusted to reflect actual results. Amounts recorded in Accrued liabilities in the Consolidated Balance Sheets for sales deductions were as follows (in millions):

	Rebates	Chargebacks	Other deductions	Total
Balance as of December 31, 2018	$ 2,589	$ 454	$ 127	$ 3,170
Amounts charged against product sales	6,825	7,090	1,292	15,207
Payments	(6,249)	(6,985)	(1,263)	(14,497)
Balance as of December 31, 2019	3,165	559	156	3,880
Amounts charged against product sales	9,167	8,223	1,818	19,208
Payments	(8,353)	(8,191)	(1,735)	(18,279)
Balance as of December 31, 2020	3,979	591	239	4,809
Amounts charged against product sales	10,195	9,619	2,065	21,879
Payments	(10,027)	(9,413)	(2,074)	(21,514)
Balance as of December 31, 2021	$ 4,147	$ 797	$ 230	$ 5,174

For the years ended December 31, 2021, 2020 and 2019, total sales deductions were 47%, 44% and 41% of gross product sales, respectively. The increase in the total sales deductions balance as of December 31, 2021, compared with December 31, 2020, was primarily driven by the impact of higher U.S. chargeback and commercial

rebate discount rates and an increase in gross sales, partially offset by timing of payments. Included in the amounts are immaterial net adjustments related to prior-year sales due to changes in estimates.

In the United States, we use wholesalers as the principal means of distributing our products to healthcare providers such as physicians or their clinics, dialysis centers, hospitals and pharmacies. Products we sell in Europe are distributed principally to hospitals and/or wholesalers depending on the distribution practice in each country where the products are sold. We monitor the inventory levels of our products at our wholesalers by using data from our wholesalers and other third parties, and we believe wholesaler inventories have been maintained at appropriate levels (generally two to three weeks) given end-user demand. Accordingly, historical fluctuations in wholesaler inventory levels have not significantly affected our method of estimating sales deductions and returns.

Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given year, can be affected by the mix of products sold.

Rebates include primarily amounts paid to payers and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements that vary by product, by payer and by individual payer plans. As we sell products, we estimate the amount of rebate we will pay based on the product sold, contractual terms, estimated patient population, historical experience and wholesaler inventory levels; and we accrue these rebates in the period the related sales are recorded. We then adjust the rebate accruals as more information becomes available and to reflect actual claims experience. Estimating such rebates is complicated, in part because of the time delay between the date of sale and the actual settlement of the liability. We believe the methodology we use to accrue for rebates is reasonable and appropriate given current facts and circumstances, but actual results may differ.

Wholesaler chargebacks relate to our contractual agreements to sell products to healthcare providers in the United States at fixed prices that are lower than the prices we charge wholesalers. When healthcare providers purchase our products through wholesalers at these reduced prices, wholesalers charge us for the difference between their purchase prices and the contractual prices between Amgen and the healthcare providers. The provision for chargebacks is based on expected sales by our wholesaler customers to healthcare providers. Accruals for wholesaler chargebacks are less difficult to estimate than rebates are, and they closely approximate actual results because chargeback amounts are fixed at the date of purchase by the healthcare providers and because we generally settle the liability for these deductions within a few weeks.

Product returns

Returns are estimated by comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. In each of the past three years, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-year sales return provisions have historically been immaterial.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is measured based on the largest benefit that is more likely than not to be realized. The amount of UTBs is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by tax authorities, new information obtained during a tax examination or resolution of an examination. We believe our estimates for uncertain tax positions are appropriate and sufficient for any assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties, when appropriate, related to UTBs in income tax expense.

Certain items are included in our tax return at different times than they are reflected in the financial statements, and they cause temporary differences between the tax bases of assets and liabilities and their reported amounts. Such temporary differences create deferred tax assets and liabilities. Deferred tax assets are generally items that can be used as tax deductions or credits in tax returns in future years but for which we have already recorded the tax benefit

in the consolidated financial statements. We establish valuation allowances against our deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities are either (i) tax expenses recognized in the consolidated financial statements for which payment has been deferred, (ii) expenses for which we have already taken a deduction on the tax return but have not yet recognized in the consolidated financial statements or (iii) liabilities for the difference between the book basis and the tax basis of the intangible assets acquired in many business combinations, because future expenses associated with these assets most often will not be tax deductible.

We are a vertically integrated enterprise with operations in the United States and various foreign jurisdictions. In the jurisdictions where we conduct operations, we are subject to income tax based on the tax laws and principles of such jurisdictions and on the functions, risks and activities performed therein. Our pretax income is therefore attributed to domestic or foreign sources based on the operations performed and risks assumed in each location and the tax laws and principles of the respective taxing jurisdictions. For example, we conduct significant operations in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes, pertaining to manufacturing, distribution and other related functions to meet our worldwide product demand. Income from our operations in Puerto Rico is subject to tax incentive grants through 2035.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010, 2011 and 2012, proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS appeals office but were unable to reach resolution. In July 2021, we filed a petition in the U.S. Tax Court to contest two duplicate Notices for 2010, 2011 and 2012 that we received in May and July 2021, which seek to increase our U.S. taxable income. The Notices seek to increase our U.S. taxable income by an amount that would result in additional federal tax of approximately $3.6 billion plus interest. Any additional tax that could be imposed would be reduced by up to approximately $900 million of repatriation tax previously accrued on our foreign earnings. We firmly believe that the IRS's positions set forth in the Notices are without merit, and we are contesting the Notices through the judicial process.

In 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015, also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico and that are similar to those proposed for the years 2010, 2011 and 2012. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS appeals office. We were unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a statutory notice of deficiency for these years as well. We expect to contest any such notice related to 2013–15 through the judicial process. We are also currently under examination by the IRS for the years 2016, 2017 and 2018 and by a number of state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our consolidated financial statements. See Part I, Item 1A. Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability;* Part II, Item 7. MD&A—Income Taxes; and Part IV—Note 6, Income taxes, to the Consolidated Financial Statements for further discussion.

Our operations are subject to the tax laws, regulations and administrative practices of the United States, the U.S. territory of Puerto Rico, U.S. state jurisdictions and other countries in which we do business. Significant changes in these rules could have a material adverse effect on our results of operations. See Part I, Item 1A. Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability*.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters such as intellectual property disputes, contractual disputes and class action suits that are complex in nature and have outcomes that are difficult to predict. We describe our legal proceedings and other matters that are significant or that we believe could become significant in Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Valuation of assets and liabilities in connection with acquisitions

We have acquired and continue to acquire intangible assets in connection with business combinations and asset acquisitions. These intangible assets consist primarily of technology associated with currently marketed human therapeutic products and IPR&D product candidates. Discounted cash flow models are typically used to determine the fair values of these intangible assets for purposes of allocating consideration paid to the net assets acquired in an acquisition. See Part IV—Note 2, Acquisitions, to the Consolidated Financial Statements. These models require the use of significant estimates and assumptions, including but not limited to:

- determining the timing and expected costs to complete in-process projects, taking into account the stage of completion at the acquisition date;
- projecting the probability and timing of obtaining marketing approval from the FDA and other regulatory agencies for product candidates;
- estimating the timing of and future net cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates to calculate the present values of the cash flows.

Significant estimates and assumptions are also required to determine the business combination date fair values of any contingent consideration obligations incurred in connection with business combinations. In addition, we must revalue these obligations each subsequent reporting period until the related contingencies are resolved and record changes in their fair values in earnings. The acquisition date fair values of contingent consideration obligations incurred or assumed in the acquisitions were determined using a combination of valuation techniques. Significant estimates and assumptions required for these valuations included but were not limited to the timing and probability of achieving regulatory milestones, product sales projections under various scenarios and discount rates used to calculate the present value of the required payments. These estimates and assumptions are required to be updated in order to revalue these contingent consideration obligations each reporting period. Accordingly, subsequent changes in underlying facts and circumstances could result in changes in these estimates and assumptions, which could have a material impact on the estimated future fair values of these obligations.

We believe the fair values used to record intangible assets acquired and contingent consideration obligations incurred in connection with business combinations and asset acquisitions are based on reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Impairment of long-lived assets

We review the carrying value of our property, plant and equipment and our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows to be generated by the long-lived asset is compared with the carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value.

Indefinite-lived intangible assets, composed of IPR&D projects acquired in a business combination that have not reached technological feasibility or that lack regulatory approval at the time of acquisition, are reviewed for impairment annually, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon establishment of technological feasibility or regulatory approval. We determine impairment by comparing the fair value of the asset to its carrying value. If the asset's carrying value exceeds its fair value, an impairment charge is recorded for the difference, and its carrying value is reduced accordingly.

Estimating future cash flows of an IPR&D product candidate for purposes of an impairment analysis requires us to make significant estimates and assumptions regarding the amount and timing of costs to complete the project and the amount, timing and probability of achieving revenues from the completed product similar to how the acquisition date fair value of the project was determined, as described above. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market these products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods which could have a material adverse effect on our results of operations.

We believe our estimations of future cash flows used for assessing impairment of long-lived assets are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

Impairment of equity method investments

We review the carrying value of our equity method investments whenever events or changes in circumstances indicate that the carrying amount of an investment may not be recoverable. We record impairment losses on our equity method investments if we deem the impairment to be other-than-temporary. We deem an impairment to be other-than-temporary based on various factors, including but not limited to, the length of time and the extent to which the fair value is below the carrying value, volatility of the security price, the financial condition of the issuer, changes in technology that may impair the earnings potential of the investment and our intent and ability to retain the investment to allow for a recovery in fair value.

We believe our judgments used in assessing impairment of equity method investments are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

Recently Issued Accounting Standards

See Part IV—Note 1, Summary of significant accounting policies, to the Consolidated Financial Statements for a discussion of recently issued accounting pronouncements not yet adopted as of December 31, 2021.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks that may result from changes in interest rates, foreign currency exchange rates and prices of equity instruments as well as changes in general economic conditions in the countries where we conduct business. To reduce certain of these risks, we enter into various types of foreign currency and interest rate derivative hedging transactions as part of our risk management program. We do not use derivatives for speculative trading purposes.

In the discussion that follows, we assumed a hypothetical change in interest rates of 100 basis points from those as of December 31, 2021 and 2020. Except as noted below, we also assumed a hypothetical 20% change in foreign currency exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2021 and 2020.

Interest-rate-sensitive financial instruments

Our portfolio of available-for-sale investments as of December 31, 2021 and 2020, was composed almost entirely of U.S. Treasury securities and money market mutual funds. The fair values of our available-for-sale investments were $7.3 billion and $9.8 billion as of December 31, 2021 and 2020, respectively. Duration is a sensitivity measure that can be used to approximate the change in the value of a security that will result from a 100 basis point change in interest rates. Applying a duration model, a hypothetical 100 basis point increase in interest rates as of December 31, 2021 and 2020, would not have resulted in a material reduction in the fair values of these securities. In addition, a hypothetical 100 basis point decrease in interest rates as of December 31, 2021 and 2020, would not result in a material effect on income in the respective ensuing year.

As of December 31, 2021, we had outstanding debt with a carrying value of $33.3 billion and a fair value of $37.9 billion. As of December 31, 2020, we had outstanding debt with a carrying value of $33.0 billion and a fair value of $39.4 billion. Our outstanding debt was composed of debt with fixed interest rates. Changes in interest rates do not affect interest expense on fixed-rate debt. Changes in interest rates would, however, affect the fair values of fixed-rate debt. A hypothetical 100 basis point decrease in interest rates relative to interest rates as of December 31, 2021 and 2020, would have resulted in an increase of $4.5 billion in the aggregate fair value of our outstanding debt on both of these dates. Analysis of the debt does not consider the impact that hypothetical changes in interest rates would have on related interest rate swap contracts and cross-currency swap contracts, discussed below.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified and were designated for accounting purposes as fair value hedges for certain of our fixed-rate debt. These interest rate swap contracts effectively converted a fixed-rate interest coupon to a floating-rate LIBOR-based coupon over the life of the respective notes. Interest rate swap contracts with aggregate notional amounts of $6.7 billion and $5.9 billion were outstanding as of December 31, 2021 and 2020, respectively. A hypothetical 100 basis point

increase in interest rates relative to interest rates as of December 31, 2021 and 2020, would have resulted in reductions in fair values of approximately $330 million and $230 million, respectively, on our interest rate swap contracts on these dates. Analysis of the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair values of debt that these interest-rate-sensitive instruments were designed to offset.

As of December 31, 2021 and 2020, we had outstanding cross-currency swap contracts with aggregate notional amounts of $3.4 billion and $4.8 billion, respectively, that hedge our foreign-currency-denominated debt and related interest payments. These contracts effectively convert interest payments and principal repayment of this debt to U.S. dollars from euros, pounds sterling and Swiss francs and are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates as of December 31, 2021 and 2020, would have resulted in reductions in the fair values of our cross-currency swap contracts of approximately $170 million and $250 million, respectively.

Foreign-currency-sensitive financial instruments

Our international operations are affected by fluctuations in the value of the U.S. dollar compared with foreign currencies, predominantly the euro. Increases and decreases in our international product sales from movements in foreign currency exchange rates are partially offset by corresponding increases or decreases in our international operating expenses. Increases and decreases in our foreign-currency-denominated assets from movements in foreign currency exchange rates are partially offset by corresponding increases or decreases in our foreign-currency-denominated liabilities. To further reduce our net exposure to foreign currency exchange rate fluctuations on our results of operations, we enter into foreign currency forward and cross-currency swap contracts.

As of December 31, 2021, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and a fair value of $3.2 billion and $3.6 billion, respectively. As of December 31, 2020, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and a fair value of $4.8 billion and $5.4 billion, respectively. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2021, would have resulted in an increase in fair value of this debt of approximately $710 million on this date and a reduction in income in the ensuing year of approximately $640 million. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2020, would have resulted in an increase in fair value of this debt of $1.1 billion on this date and a reduction in income in the ensuing year of $1.0 billion. The impact on income from these hypothetical changes in foreign currency exchange rates would be substantially offset by the impact such changes would have on related cross-currency swap contracts, which are in place for the related foreign-currency-denominated debt.

We have cross-currency swap contracts that are designated as cash flow hedges of our debt denominated in euros, pounds sterling and Swiss francs, with aggregate notional amounts of $3.4 billion and $4.8 billion as of December 31, 2021 and 2020, respectively. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would have resulted in reductions in the fair values of these contracts of approximately $700 million and $1.1 billion on these dates, respectively. The impact of this hypothetical adverse movement in foreign currency exchange rates on ensuing years' income from these contracts would be fully offset by corresponding hypothetical changes in the carrying amounts of the related hedged debt.

We enter into foreign currency forward contracts that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2021, the fair values of these contracts were a $183 million asset and a $39 million liability. As of December 31, 2020, the fair values of these contracts were a $28 million asset and a $237 million liability. As of December 31, 2021, we had primarily euro-based open foreign currency forward contracts with notional amounts of $5.7 billion. As of December 31, 2020, we had primarily euro-based open foreign currency forward contracts with notional amounts of $5.1 billion. With regard to foreign currency forward contracts that were open as of December 31, 2021, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2021, would have resulted in a reduction in fair value of these contracts of approximately $1.1 billion on this date and in the ensuing year, a reduction in income of approximately $390 million. With regard to contracts that were open as of December 31, 2020, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2020, would have resulted in a reduction in fair value of these contracts of $1.1 billion on this date and in the ensuing year, a reduction in income of $420 million. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign-currency-sensitive instruments were designed to offset.

As of December 31, 2021 and 2020, we had open, short-duration, foreign currency forward contracts that mature in one month or less, that had notional amounts of $0.7 billion and $1.0 billion, respectively, and that hedged fluctuations of certain assets and liabilities denominated in foreign currencies but were not designated as hedges for

accounting purposes. These contracts had no material net unrealized gains or losses as of December 31, 2021 and 2020. With regard to these foreign currency forward contracts that were open as of December 31, 2021 and 2020, a hypothetical 5% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would not have a material effect on the fair values of these contracts or related income in the respective ensuing years. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on assets and liabilities that these foreign-currency-sensitive instruments were designed to offset.

Market-price-sensitive financial instruments

As of December 31, 2021 and 2020, we were exposed to price risk on equity securities included in our portfolio of investments, which were acquired primarily for the promotion of business and strategic objectives. These investments include publicly and privately held small-capitalization stocks, limited partnerships that invest in early-stage biotechnology companies and our investment in BeiGene. A 20% decrease in the aggregate value of our equity investment portfolio as of December 31, 2021 and 2020, would result in losses in fair value of approximately $1.4 billion and $1.2 billion, respectively.

Counterparty credit risks

Our financial instruments, including derivatives, are subject to counterparty credit risk, which we consider as part of the overall fair value measurement. Our financial risk management policy limits derivative transactions by requiring that transactions be made only with institutions with minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch; and it places exposure limits on the amount with any individual counterparty. In addition, we have an investment policy that limits investments to certain types of debt and money market instruments issued by institutions with investment-grade credit ratings and places restriction on maturities and concentrations by asset class and issuer.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is incorporated herein by reference to the financial statements and schedule listed in Item 15(a)1 and (a)2 of Part IV and included in this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under the Securities Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, Amgen's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2021.

Management determined that as of December 31, 2021, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP in the United States. However, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and reporting.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2021. In making this assessment, management used the criteria set forth by the COSO in Internal Control—Integrated Framework (2013 framework). Based on our assessment, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

The effectiveness of the Company's internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing below, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2021.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Amgen Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Amgen Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Amgen Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 and our report dated February 16, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Los Angeles, California
February 16, 2022

Item 9B. **OTHER INFORMATION**

Not applicable.

PART III

Item 10. **DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Information about our Directors is incorporated by reference from the section entitled ITEM 1—ELECTION OF DIRECTORS in our Proxy Statement for the 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2021 (the Proxy Statement). Information about the procedures by which stockholders may recommend nominees for the Board of Directors is incorporated by reference from APPENDIX A —AMGEN INC. BOARD OF DIRECTORS GUIDELINES FOR DIRECTOR QUALIFICATIONS AND EVALUATIONS and OTHER MATTERS—Stockholder Proposals for the 2023 Annual Meeting in our Proxy Statement. Information about our Audit Committee, members of the committee and our Audit Committee financial experts is incorporated by reference from the section entitled CORPORATE GOVERNANCE—Audit Committee in our Proxy Statement. Information about our executive officers is contained in the discussion entitled Part I—Item 1. Business—Information about our Executive Officers.

Code of Ethics

We maintain a Code of Ethics for the Chief Executive Officer and Senior Financial Officers applicable to our principal executive officer, principal financial officer, principal accounting officer or controller and other persons performing similar functions. To view this code of ethics free of charge, please visit our website at www.amgen.com. (The website address is not intended to function as a hyperlink, and the information contained in our website is not intended to be a part of this filing.) We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to or a waiver from a provision of this code of ethics, if any, by posting such information on our website as set forth above.

Item 11. **EXECUTIVE COMPENSATION**

Information about director and executive compensation is incorporated by reference from the section entitled EXECUTIVE COMPENSATION in our Proxy Statement. Information about compensation committee matters is incorporated by reference from the sections entitled CORPORATE GOVERNANCE—Compensation and Management Development Committee and CORPORATE GOVERNANCE—Compensation Committee Report in our Proxy Statement.

Item 12. **SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table sets forth certain information as of December 31, 2021, concerning the shares of our common stock that may be issued under any form of award granted under our equity compensation plans in effect as of December 31, 2021 (including upon the exercise of options, upon the vesting of awards of RSUs or when performance units are earned and related dividend equivalents have been granted).

	(a)	(b)	(c)
Plan category	**Number of securities to be issued upon exercise of outstanding options and rights**	**Weighted-average exercise price of outstanding options and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**
Equity compensation plans approved by Amgen security holders:			
Amended and Restated 2009 Equity Incentive Plan[1]	10,217,143	$ 197.27	18,987,053
Amended and Restated 1991 Equity Incentive Plan[2]	3,550	—	—
Amended and Restated Employee Stock Purchase Plan	—	—	4,280,585
Total approved plans	10,220,693	197.27	23,267,638
Equity compensation plan not approved by Amgen security holders:			
Amgen Profit Sharing Plan for Employees in Ireland[3]	—	—	242,172
Total unapproved plans	—	—	242,172
Total all plans	10,220,693	$ 197.27	23,509,810

(1) The Amended and Restated 2009 Equity Incentive Plan employs a fungible share-counting formula for determining the number of shares available for issuance under the plan. In accordance with this formula, each option or stock appreciation right counts as one share, while each RSU, performance unit or dividend equivalent counts as 1.9 shares. The number under column (a) represents the actual number of shares issuable under our outstanding awards without giving effect to the fungible share-counting formula. The number under column (c) represents the number of shares available for issuance under this plan based on each such available share counting as one share. Commencing with the grants made in April 2012, RSUs and performance units accrue dividend equivalents that are payable in shares only to the extent and when the underlying RSUs vest or underlying performance units have been earned and the related shares are issued to the grantee. The performance units granted under this plan are earned based on the accomplishment of specified performance goals at the end of their respective three-year performance periods; the number of performance units granted represent target performance, and the maximum number of units that could be earned based on our performance is 200% of the performance units granted in 2019, 2020 and 2021.

As of December 31, 2021, the number of outstanding awards under column (a) includes (i) 5,138,659 shares issuable upon the exercise of outstanding options with a weighted-average exercise price of $197.27; (ii) 3,362,823 shares issuable upon the vesting of outstanding RSUs (including 292,972 related dividend equivalents); and (iii) 1,715,660 shares subject to outstanding 2019, 2020 and 2021 performance units (including 88,269 related dividend equivalents). The weighted-average exercise price shown in column (b) is for the outstanding options only. The number of available shares under column (c) represents the number of shares that remain available for future issuance under this plan as of December 31, 2021, employing the fungible share formula and presumes the issuance of target shares under the performance units granted in 2019, 2020 and 2021 and related dividend equivalents. The numbers under columns (a) and (c) do not give effect to

the additional shares that could be issuable in the event above target performance on the performance goals under these outstanding performance units is achieved. Maximum performance under these goals could result in 200% of target shares being awarded for performance units granted in 2019, 2020 and 2021.

(2) This plan has terminated as to future grants. The number under column (a) with respect to this plan includes 3,550 shares issuable upon the settlement of deferred RSUs (including 774 related dividend equivalents).

(3) The Profit Sharing Plan was approved by the Board of Directors on July 28, 2011. The Profit Sharing Plan permits eligible employees of the Company's subsidiaries located in Ireland who participate in the Profit Sharing Plan to apply a portion of their qualifying bonus and salary to the purchase of the Company's common stock on the open market at the market price by a third-party trustee as described in the Profit Sharing Plan.

Security Ownership of Directors and Executive Officers and Certain Beneficial Owners

Information about security ownership of certain beneficial owners and management is incorporated by reference from the sections entitled SECURITY OWNERSHIP OF DIRECTORS AND EXECUTIVE OFFICERS and SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS in our Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information about certain relationships and related transactions and director independence is incorporated by reference from the sections entitled CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS and CORPORATE GOVERNANCE—Director Independence in our Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information about the fees for professional services rendered by our independent registered public accountants is incorporated by reference from the section entitled AUDIT MATTERS—Independent Registered Public Accountants in our Proxy Statement.

PART IV

Item 15. **EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a)1. Index to Financial Statements

The following Consolidated Financial Statements are included herein:

	Page number
Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	F-1
Consolidated Statements of Income for each of the three years in the period ended December 31, 2021	F-4
Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2021	F-5
Consolidated Balance Sheets as of December 31, 2021 and 2020	F-6
Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2021	F-7
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2021	F-8
Notes to Consolidated Financial Statements	F-9

(a)2. Index to Financial Statement Schedules

The following Schedule is filed as part of this Annual Report on Form 10-K:

	Page number
Schedule II. Valuation and Qualifying Accounts	F-55

All other schedules are omitted because they are not applicable, not required or because the required information is included in the consolidated financial statements or notes thereto.

(a)3. Exhibits

Exhibit No.	Description
2.1	Asset Purchase Agreement, dated August 25, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.2	Amendment No. 1 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on October 17, 2019 and incorporated herein by reference.)
2.3	Amendment No. 2 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.4	Letter Agreement, dated November 21, 2019, by and between Amgen Inc. and the parties named therein re: Treatment of Certain Product Inventory in connection with Amgen's acquisition of Otezla (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.5	Irrevocable Guarantee, dated August 25, 2019, by and between Amgen Inc. and Bristol-Myers Squibb Company. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.6	Agreement and Plan of Merger, dated July 27, 2021, by and among Amgen Inc., Teneobio, Inc., Tuxedo Merger Sub, Inc., and Fortis Advisors LLC. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential)(Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2021 on November 3, 2021 and incorporated herein by reference.)

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.6	Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.7	Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.8	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.9	Officers' Certificate of Amgen Inc., dated May 30, 2007, including form of the Company's 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
4.10	Officers' Certificate of Amgen Inc., dated May 23, 2008, including form of the Company's 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)
4.11	Officers' Certificate of Amgen Inc., dated January 16, 2009, including form of the Company's 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)
4.12	Officers' Certificate of Amgen Inc., dated March 12, 2010, including form of the Company's 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.)
4.13	Officers' Certificate of Amgen Inc., dated September 16, 2010, including form of the Company's 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)
4.14	Officers' Certificate of Amgen Inc., dated June 30, 2011, including form of the Company's 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)
4.15	Officers' Certificate of Amgen Inc., dated November 10, 2011, including form of the Company's 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)
4.16	Officers' Certificate of Amgen Inc., dated December 5, 2011, including form of the Company's 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)
4.17	Officers' Certificate of Amgen Inc., dated May 15, 2012, including form of the Company's 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)
4.18	Officers' Certificate of Amgen Inc., dated September 13, 2012, including form of the Company's 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)

Exhibit No.	Description
4.19	Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
4.20	Officers' Certificate of Amgen Inc., dated May 22, 2014, including form of the Company's 3.625% Senior Notes due 2024. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
4.21	Officer's Certificate of Amgen Inc., dated May 1, 2015, including forms of the Company's 3.125% Senior Notes due 2025 and 4.400% Senior Notes due 2045. (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.)
4.22	Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including form of the Company's 2.000% Senior Notes due 2026. (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.)
4.23	Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.24	Terms of the Bonds for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.25	Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.26	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated herein by reference.)
4.28	Officer's Certificate of Amgen Inc., dated as of February 21, 2020, including forms of the Company's 1.900% Senior Notes due 2025, 2.200% Senior Notes due 2027, 2.450% Senior Notes due 2030, 3.150% Senior Notes due 2040 and 3.375% Senior Notes due 2050. (Filed as an exhibit to Form 8-K on February 21, 2020 and incorporated herein by reference.)
4.29	Officer's Certificate of Amgen Inc., dated as of May 6, 2020, including form of the Company's 2.300% Senior Notes due 2031. (Filed as an exhibit to Form 8-K on May 6, 2020 and incorporated herein by reference.)
4.30	Officer's Certificate of Amgen Inc., dated as of August 17, 2020, including forms of the Company's 2.770% Senior Notes due 2053. (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)
4.31	Registration Rights Agreement, dated as of August 17, 2020, by and among Amgen Inc., BofA Securities, Inc. and J.P. Morgan Securities LLC, as lead dealer managers, and BNP Paribas Securities Corp., Deutsche Bank Securities Inc., RBC Capital Markets, LLC, Blaylock Van, LLC and Siebert Williams Shank & Co., LLC, as co-dealer managers. (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)
4.32*	Description of Amgen Inc.'s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1+	Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
10.2+	First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.)
10.3+	Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)
10.4+*	Form of Grant of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended and Restated on December 2, 2021.)

Exhibit No.	Description
10.5+*	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended and Restated on December 2, 2021.)
10.6+	Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.7+*	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended and Reinstated on December 2, 2021.)
10.8+	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended and Restated on October 21, 2020.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 and incorporated herein by reference.)
10.9+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.10+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.11+	Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.12+	Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.13+	First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.14+	Second Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 23, 2019. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.15+*	Third Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 20, 2021.
10.16+	Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.)
10.17+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.18+	First Amendment to the Amgen Inc. Executive Incentive Plan, effective December 13, 2012. (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.)
10.19+	Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.20+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.21+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.22+	Second Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective January 1, 2020. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)

Exhibit No.	Description
10.23+*	Third Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective January 1, 2022.
10.24+	Agreement between Amgen Inc. and Peter Griffith, dated October 18, 2019. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)
10.25+*	Aircraft Time Sharing Agreement, dated December 3, 2021, by and between Amgen Inc. and Robert A. Bradway.
10.26	Second Amended and Restated Credit Agreement, dated December 12, 2019, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent. (Filed as an exhibit to Form 8-K on December 12, 2019 and incorporated herein by reference.)
10.27	Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)
10.28	Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.29	Letter Agreement, dated June 25, 2019, by and between Amgen Inc. and UCB Celltech (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2019 on July 31, 2019 and incorporated herein by reference.)
10.30	Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)
10.31	Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.32	Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.33	Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.34	Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.35	Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
10.36	Side Letter Regarding Collaboration Agreement and Stivarga Agreement, dated February 13, 2020, by and between Onyx Pharmaceuticals, Inc. and Bayer HealthCare LLC. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)
10.37	Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.38	Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

Exhibit No.	Description
10.39	Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.40	Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.41	Amendment No. 3 to the Exclusive License and Collaboration Agreement, dated January 31, 2022, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential). (Filed as an exhibit to the Company's Current Report on Form 8-K on January 31, 2022 and incorporated herein by reference.)
10.42	Collaboration Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene Switzerland GmbH, a wholly-owned subsidiary of BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.43	Guarantee, dated as of October 31, 2019, made by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.44	Share Purchase Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.45	Amendment No. 1 to Share Purchase Agreement, dated December 6, 2019, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.46	Restated Amendment No. 2 to Share Purchase Agreement, dated September 24, 2020, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2020 on October 29, 2020 and incorporated herein by reference.)
10.47	Collaboration Agreement dated March 30, 2012 by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, a wholly owned subsidiary of AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2012 on May 8, 2012 and incorporated herein by reference.)
10.48	Amendment No. 1 to the Collaboration Agreement, dated October 1, 2014, by and among Amgen Inc., AstraZeneca Collaboration Ventures, LLC and AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2014 on February 19, 2015 and incorporated herein by reference.)
10.49	Amendment Nos. 2 through 6 to the March 30, 2012 Collaboration Agreement between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, dated May 2 and 27 and October 2, 2016, January 31, 2018, and May 15, 2020, respectively (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2020 on July 29, 2020 and incorporated herein by reference.)
10.50	Amendment No. 7 to the Collaboration Agreement, dated December 17, 2020, by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 and incorporated herein by reference.)
10.51*	Amendment No. 8 to the Collaboration Agreement, dated November 19, 2021, by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.)

Exhibit No.	Description
10.52	License and Collaboration Agreement, dated June 1, 2021, by and between Amgen Inc. and Kyowa Kirin Co., Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2021 on August 4, 2021 and incorporated herein by reference.)
21*	Subsidiaries of the Company.
23	Consent of the Independent Registered Public Accounting Firm. The consent is set forth on page 89 of this Annual Report on the 10-K.
24	Power of Attorney. The Power of Attorney is set forth on page 90 of this Annual Report on Form 10-K.
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

(* = filed herewith)
(** = furnished herewith and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended)
(+ = management contract or compensatory plan or arrangement)

Item 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMGEN INC.
(Registrant)

Date: February 16, 2022

By: /s/ PETER H. GRIFFITH

Peter H. Griffith
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-3 No. 333-236351) of Amgen Inc.,
- Registration Statement (Form S-8 No. 333-159377) pertaining to the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan,
- Registration Statement (Form S-8 No. 33-39183) pertaining to the Amgen Inc. Amended and Restated Employee Stock Purchase Plan,
- Registration Statements (Form S-8 No. 33-39104, as amended by Form S-8 Nos. 333-144581 and 333-216719) pertaining to the Amgen Retirement and Savings Plan,
- Registration Statements (Form S-8 Nos. 33-47605, 333-144580 and 333-216715) pertaining to The Retirement and Savings Plan for Amgen Manufacturing, Limited (formerly known as the Retirement and Savings Plan for Amgen Manufacturing, Inc.),
- Registration Statements (Form S-8 Nos. 333-81284, 333-177868, 333-216723 and 333-260723) pertaining to the Amgen Nonqualified Deferred Compensation Plan, and
- Registration Statement (Form S-8 Nos. 333-176240 and 333-260724) pertaining to the Amgen Profit Sharing Plan for Employees in Ireland;

of our reports dated February 16, 2022, with respect to the consolidated financial statements of Amgen Inc. and the effectiveness of internal control over financial reporting of Amgen Inc. included in this Annual Report (Form 10-K) of Amgen Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Los Angeles, California
February 16, 2022

EXHIBIT 24

POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Robert A. Bradway, Peter H. Griffith and Jonathan P. Graham, or any of them, his or her attorney-in-fact, each with the power of substitution and re-substitution, for him or her in any and all capacities, to sign any amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/S/ ROBERT A. BRADWAY **Robert A. Bradway**	Chairman of the Board, Chief Executive Officer and President, and Director (Principal Executive Officer)	2/16/2022
/S/ PETER H. GRIFFITH **Peter H. Griffith**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	2/16/2022
/S/ LINDA H. LOUIE **Linda H. Louie**	Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)	2/16/2022
/S/ WANDA M. AUSTIN **Wanda M. Austin**	Director	2/16/2022
/S/ BRIAN J. DRUKER **Brian J. Druker**	Director	2/16/2022
/S/ ROBERT A. ECKERT **Robert A. Eckert**	Director	2/16/2022
/S/ GREG C. GARLAND **Greg C. Garland**	Director	2/16/2022
/S/ CHARLES M. HOLLEY, JR. **Charles M. Holley, Jr.**	Director	2/16/2022
/S/ S. OMAR ISHRAK **S. Omar Ishrak**	Director	2/16/2022
/S/ TYLER JACKS **Tyler Jacks**	Director	2/16/2022
/S/ ELLEN J. KULLMAN **Ellen J. Kullman**	Director	2/16/2022
/S/ AMY E. MILES **Amy E. Miles**	Director	2/16/2022
/S/ RONALD D. SUGAR **Ronald D. Sugar**	Director	2/16/2022
/S/ R. SANDERS WILLIAMS **R. Sanders Williams**	Director	2/16/2022

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Amgen Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amgen Inc. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 16, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Sales deductions

Description of the Matter

As of December 31, 2021, the Company recorded accrued sales deductions of $5.2 billion. As described in Note 1 to the financial statements under the caption "Product sales and sales deductions," revenues from product sales are recognized net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively sales deductions), which are established at the time of sale.

Auditing the estimation of sales deductions, which are netted against product sales, is complex, requires significant judgment, and the amounts involved are material to the financial statements taken as a whole. Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, and is based on an amount that reflects the consideration to which the Company expects to be entitled, which represents an amount that is net of accruals for estimated sales deductions. The estimated sales deductions are based on current contractual and statutory requirements, market events and trends, internal and external historical data, and forecasted customer buying patterns.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the sales deduction processes. This included testing controls over management's review of significant assumptions and inputs used in the estimate of sales deductions, including actual sales, contractual terms, historical experience, wholesaler inventory levels, demand data and estimated patient population. We also tested management's controls over the accuracy of forecasting demand activity as well as the completeness and accuracy of the significant components included in the final sales deduction estimates.

To test management's estimated sales deductions, we obtained management's calculations for the respective estimates and performed the following procedures, among others. We tested management's estimation process over the determination of sales discount accruals by developing an independent expectation of the estimated accrual balances, including comparing accrual balances recorded by management to those implied by historical payment trends, performing a lookback analysis using actual historical data to evaluate the forecasted amounts, assessing subsequent events to determine whether there was any new information that would require adjustment to the initial accruals, evaluating trends in actual sales and discount accrual balances, comparing cash receipts to product sales, confirming terms and conditions for a sample of contracts with the Company's customers, testing a sample of credits issued and payments made throughout the year, and agreeing rates to underlying contract terms.

Unrecognized tax benefits

Description of the Matter

As discussed in Notes 1 and 6 to the consolidated financial statements, the Company operates in various jurisdictions in which differing interpretations of complex tax laws and regulations create uncertainty and necessitate the use of significant judgment in the determination of the Company's unrecognized tax benefits related to allocation of profits among various jurisdictions ("transfer pricing"), particularly in the U.S. federal tax jurisdiction where the Company has significant assets and operations. In this regard, the Company uses significant judgment in (1) determining whether a tax position's technical merits are more-likely-than-not to be sustained and (2) measuring the amount of tax benefit that qualifies for recognition. As of December 31, 2021, the Company accrued $3.5 billion of gross unrecognized tax benefits including those related to transfer pricing. Auditing the assessment of the technical merits and measurement of the Company's unrecognized tax benefits is challenging and can be complex, highly judgmental, and based on interpretations of tax laws and regulations and application of those interpretations to the Company's facts and circumstances.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the Company's process to assess the technical merits of its tax positions, as well as management's process to measure the unrecognized tax benefits of those tax positions, particularly in regard to transfer pricing. This included testing controls over management's review of the inputs, calculations, assumptions and methods selected to measure the amount of tax benefits that qualify for recognition.

We involved tax and transfer pricing specialists to assist in assessing the technical merits and measurement of certain of the Company's unrecognized tax benefits. Depending on the nature of the specific tax position and, as applicable, developments with the relevant tax authorities, our procedures included obtaining and reviewing the Company's correspondence with such tax authorities and evaluating certain third-party advice to support the Company's evaluations and recorded positions. We used our knowledge of and experience with how the income tax laws and regulations related to transfer pricing are applied by the relevant tax authorities to evaluate the Company's accounting for its unrecognized tax benefits. We evaluated developments in the applicable regulatory environments to assess potential effects on the Company's recorded positions. We analyzed the assumptions and data used by the Company when it determined the amount of tax benefits to recognize, including applicable interest and penalties, and we tested the accuracy of those underlying calculations. We have also evaluated the Company's income tax disclosures included in Note 6 in relation to these matters.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1980.
Los Angeles, California
February 16, 2022

AMGEN INC.

CONSOLIDATED STATEMENTS OF INCOME

Years ended December 31, 2021, 2020 and 2019

(In millions, except per-share data)

	2021	2020	2019
Revenues:			
Product sales	$ 24,297	$ 24,240	$ 22,204
Other revenues	1,682	1,184	1,158
Total revenues	25,979	25,424	23,362
Operating expenses:			
Cost of sales	6,454	6,159	4,356
Research and development	4,819	4,207	4,116
Acquired in-process research and development	1,505	—	—
Selling, general and administrative	5,368	5,730	5,150
Other	194	189	66
Total operating expenses	18,340	16,285	13,688
Operating income	7,639	9,139	9,674
Other income (expense):			
Interest expense, net	(1,197)	(1,262)	(1,289)
Other income, net	259	256	753
Income before income taxes	6,701	8,133	9,138
Provision for income taxes	808	869	1,296
Net income	$ 5,893	$ 7,264	$ 7,842
Earnings per share:			
Basic	$ 10.34	$ 12.40	$ 12.96
Diluted	$ 10.28	$ 12.31	$ 12.88
Shares used in the calculation of earnings per share:			
Basic	570	586	605
Diluted	573	590	609

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Years ended December 31, 2021, 2020 and 2019

(In millions)

	2021	2020	2019
Net income	$ 5,893	$ 7,264	$ 7,842
Other comprehensive income (loss), net of reclassification adjustments and taxes:			
(Losses) gains on foreign currency translation	(135)	9	(48)
Gains (losses) on cash flow hedges	324	(438)	(66)
(Losses) gains on available-for-sale securities	(1)	(21)	360
Other	1	(7)	(5)
Other comprehensive income (loss), net of taxes	189	(457)	241
Comprehensive income	$ 6,082	$ 6,807	$ 8,083

See accompanying notes.

AMGEN INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2021 and 2020

(In millions, except per-share data)

	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,989	$ 6,266
Marketable securities	48	4,381
Trade receivables, net	4,895	4,525
Inventories	4,086	3,893
Other current assets	2,367	2,079
Total current assets	19,385	21,144
Property, plant and equipment, net	5,184	4,889
Intangible assets, net	15,182	16,587
Goodwill	14,890	14,689
Other noncurrent assets	6,524	5,639
Total assets	$ 61,165	$ 62,948
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,366	$ 1,421
Accrued liabilities	10,731	10,141
Current portion of long-term debt	87	91
Total current liabilities	12,184	11,653
Long-term debt	33,222	32,895
Long-term tax liabilities	6,594	6,968
Other noncurrent liabilities	2,465	2,023
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value per share; 2,750.0 shares authorized; outstanding—558.3 shares in 2021 and 578.3 shares in 2020	32,096	31,802
Accumulated deficit	(24,600)	(21,408)
Accumulated other comprehensive loss	(796)	(985)
Total stockholders' equity	6,700	9,409
Total liabilities and stockholders' equity	$ 61,165	$ 62,948

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended December 31, 2021, 2020 and 2019

(In millions, except per-share data)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total
Balance as of December 31, 2018	629.6	$ 31,246	$ (17,977)	$ (769)	$ 12,500
Net income	—	—	7,842	—	7,842
Other comprehensive income, net of taxes	—	—	—	241	241
Dividends declared on common stock ($5.95 per share)	—	—	(3,555)	—	(3,555)
Issuance of common stock in connection with the Company's equity award programs	2.0	97	—	—	97
Stock-based compensation expense	—	323	—	—	323
Tax impact related to employee stock-based compensation expense	—	(135)	—	—	(135)
Repurchases of common stock	(40.2)	—	(7,640)	—	(7,640)
Balance as of December 31, 2019	591.4	31,531	(21,330)	(528)	9,673
Cumulative effect of changes in accounting principles, net of taxes	—	—	(2)	—	(2)
Net income	—	—	7,264	—	7,264
Other comprehensive loss, net of taxes	—	—	—	(457)	(457)
Dividends declared on common stock ($6.56 per share)	—	—	(3,843)	—	(3,843)
Issuance of common stock in connection with the Company's equity award programs	2.1	91	—	—	91
Stock-based compensation expense	—	349	—	—	349
Tax impact related to employee stock-based compensation expense	—	(169)	—	—	(169)
Repurchases of common stock	(15.2)	—	(3,497)	—	(3,497)
Balance as of December 31, 2020	578.3	31,802	(21,408)	(985)	9,409
Net income	—	—	5,893	—	5,893
Other comprehensive income, net of taxes	—	—	—	189	189
Dividends declared on common stock ($7.22 per share)	—	—	(4,098)	—	(4,098)
Issuance of common stock in connection with the Company's equity award programs	1.7	82	—	—	82
Stock-based compensation expense	—	361	—	—	361
Tax impact related to employee stock-based compensation expense	—	(149)	—	—	(149)
Repurchases of common stock	(21.7)	—	(4,987)	—	(4,987)
Balance as of December 31, 2021	558.3	$ 32,096	$ (24,600)	$ (796)	$ 6,700

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2021, 2020 and 2019

(In millions)

	2021	2020	2019
Cash flows from operating activities:			
Net income	$ 5,893	$ 7,264	$ 7,842
Depreciation, amortization and other	3,398	3,601	2,206
Stock-based compensation expense	341	330	308
Deferred income taxes	(453)	(287)	(289)
Acquired in-process research and development	1,505	—	—
Other items, net	(229)	(195)	(186)
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	(429)	(427)	(504)
Inventories	(165)	(215)	(66)
Other assets	(237)	129	10
Accounts payable	(69)	45	164
Accrued income taxes, net	(854)	(249)	(585)
Long-term tax liabilities	204	(482)	(146)
Other liabilities	356	983	396
Net cash provided by operating activities	9,261	10,497	9,150
Cash flows from investing activities:			
Purchases of marketable securities	(8,900)	(8,477)	(9,394)
Proceeds from sales of marketable securities	4,403	2,597	8,842
Proceeds from maturities of marketable securities	8,831	4,381	20,548
Purchases of property, plant and equipment	(880)	(608)	(618)
Cash paid for acquisitions, net of cash acquired	(2,529)	—	(13,617)
Purchases of equity method investments	(157)	(3,219)	(24)
Other	(35)	(75)	(28)
Net cash provided by (used in) investing activities	733	(5,401)	5,709
Cash flows from financing activities:			
Net proceeds from issuance of debt	4,945	8,914	—
Repayment of debt	(4,150)	(6,450)	(4,514)
Repurchases of common stock	(4,975)	(3,486)	(7,702)
Dividends paid	(4,013)	(3,755)	(3,509)
Other	(78)	(90)	(42)
Net cash used in financing activities	(8,271)	(4,867)	(15,767)
Increase (decrease) in cash and cash equivalents	1,723	229	(908)
Cash and cash equivalents at beginning of year	6,266	6,037	6,945
Cash and cash equivalents at end of year	$ 7,989	$ 6,266	$ 6,037

See accompanying notes.

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2021

1. Summary of significant accounting policies

Business

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. We operate in one business segment: human therapeutics.

Principles of consolidation

The consolidated financial statements include the accounts of Amgen as well as its majority-owned subsidiaries. In determining whether we are the primary beneficiary of a variable interest entity, we consider whether we have both the power to direct activities of the entity that most significantly impact the entity's economic performance and the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. We do not have any significant interests in any variable interest entities of which we are the primary beneficiary. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Revenues

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that an adjustment is appropriate. Accruals are also adjusted to reflect actual results. Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given period, can be affected by the mix of products sold. Included in sales deductions are immaterial net adjustments related to prior-period sales due to changes in estimates.

Returns are estimated through comparison of historical return data with their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. Historically, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-period sales return provisions have historically been immaterial.

Our payment terms vary by types and locations of customers and by products or services offered. Payment terms differ by jurisdiction and customer, but payment is generally required in a term ranging from 30 to 120 days from date of shipment or satisfaction of the performance obligation. For certain products or services and certain customer types, we may require payment before products are delivered or services are rendered to customers.

Indirect taxes collected from customers and remitted to government authorities that are related to sales of the Company's products, primarily in Europe, are excluded from revenues.

As a practical expedient, sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in SG&A expense in the Consolidated Statements of Income.

Other revenues

Other revenues consist primarily of royalty income and corporate partner revenues. Royalties from licensees are based on third-party sales of licensed products and are recorded when the related third-party product sale occurs. Royalty income is estimated based on historical and forecasted sales trends. Corporate partner revenues are composed mainly of license fees and milestones earned and our share of commercial profits generated from collaborations. See Arrangements with multiple-performance obligations, discussed below.

Arrangements with multiple-performance obligations

From time to time, we enter into arrangements for the R&D, manufacture and/or commercialization of products and product candidates. Such arrangements may require us to deliver various rights, services and/or goods, including intellectual property rights/licenses, R&D services, manufacturing services and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to Amgen in the form of nonrefundable, upfront license fees; development and commercial-performance milestone payments; royalty payments; and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or by using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods or services is transferred. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. We utilize the sales- and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

Research and development costs

R&D costs are expensed as incurred and primarily include salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems' costs; and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs and cost recoveries associated with third-party R&D arrangements, including upfront fees and milestones paid to third parties in connection with technologies that had not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 8, Collaborations.

Selling, general and administrative costs

SG&A costs are primarily composed of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses; the U.S. healthcare reform federal excise fee on Branded Prescription Pharmaceutical Manufacturers and Importers; and other general and administrative costs. Advertising costs are expensed as incurred and were $843 million, $962 million and $789 million during the years ended December 31, 2021, 2020 and 2019, respectively. SG&A expenses also include costs and cost recoveries associated with marketing and promotion efforts under certain collaborative arrangements. Net payment or reimbursement of SG&A costs is recognized when the obligations are incurred or we become entitled to the cost recovery. See Note 8, Collaborations.

Leases

At inception of a contract, we determine whether an arrangement is or contains a lease. For all leases, we determine the classification as either operating or financing. Operating leases are included in Other noncurrent assets, Accrued liabilities and Other noncurrent liabilities in our Consolidated Balance Sheets.

ROU assets represent our right to use an underlying asset for the lease term, and lease liabilities represent our obligation to make lease payments under the lease. Lease recognition occurs at the commencement date, and lease liability amounts are based on the present value of lease payments made during the lease term. Our lease terms may include options to extend or terminate a lease when it is reasonably certain that we will exercise that option. Because most of our leases do not provide information to determine an implicit interest rate, we use our incremental borrowing rate in determining the present value of lease payments. ROU assets also include any lease payments made prior to the commencement date less lease incentives received. Operating lease expense is recognized on a straight-line basis over the lease term.

We have lease agreements with both lease and nonlease components, which are generally accounted for together as a single lease component. In addition, for certain vehicle and equipment leases, we apply a portfolio approach to determine the lease term and discount rate.

Stock-based compensation

We have stock-based compensation plans under which various types of equity-based awards are granted, including RSUs, performance units and stock options. The fair values of RSUs and stock option awards, which are subject only to service conditions with graded vesting, are recognized as compensation expense, generally on a straight-line basis over the service period, net of estimated forfeitures. The fair values of performance unit awards are recognized as compensation expense, generally on a straight-line basis from the grant date to the end of the performance period. See Note 4, Stock-based compensation.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate. Significant judgment is required in determining our provision for income taxes and income tax assets and liabilities, including evaluating uncertainties in the application of accounting principles and complex tax laws. Deferred income taxes are recorded for the expected tax consequences of temporary differences between the bases of assets and liabilities, as well as for loss and tax credit carryforwards for financial reporting purposes and amounts recognized for income tax purposes. We record a valuation allowance to reduce our deferred tax assets to the amount of future tax benefit that is more likely than not to be realized.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by tax authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of UTBs is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by tax authorities, new information obtained during a tax examination or resolution of an examination. We recognize both accrued interest and penalties, when appropriate, related to UTBs in income tax expense. See Note 6, Income taxes.

Acquisitions

We first determine whether a set of assets acquired constitute a business and should be accounted for as a business combination. If the assets acquired do not constitute a business, we account for the transaction as an asset acquisition. Business combinations are accounted for by means of the acquisition method of accounting. Under the acquisition method, assets acquired, including IPR&D projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with a business combination (including the assumption of an acquiree's liability arising from an acquisition it consummated prior to our acquisition) are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies have been resolved. The resulting changes in fair values are recorded in earnings. In contrast, asset acquisitions are accounted for by using a cost accumulation and allocation model. Under this model, the cost of the acquisition is allocated to the assets acquired and liabilities assumed. IPR&D projects with no alternative future use are recorded in R&D expense upon acquisition, and contingent consideration obligations incurred in connection with an asset acquisition are recorded when it is probable that they will occur and they can be reasonably estimated. See Note 2, Acquisitions, and Note 17, Fair value measurement.

Cash equivalents

We consider cash equivalents to be only those investments that are highly liquid, that are readily convertible to cash and that mature within three months from the date of purchase.

Interest-bearing securities

We consider our interest-bearing securities investment portfolio as available-for-sale, and accordingly, these investments are recorded at fair value, with unrealized gains and losses recorded in AOCI. Investments with maturities beyond one year may be classified as short-term marketable securities in the Consolidated Balance Sheets due to their highly liquid nature and because they represent the Company's investments that are available for current operations. See Note 9, Investments, and Note 17, Fair value measurement.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner that approximates the first-in, first-out method. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. See Note 10, Inventories.

Derivatives

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Consolidated Balance Sheets. The accounting for changes in the fair value of a derivative instrument depends on whether the derivative has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of hedging relationship. For derivatives formally designated as hedges, we assess both at inception and quarterly thereafter whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item. Our derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings. See Note 17, Fair value measurement, and Note 18, Derivative instruments.

Property, plant and equipment, net

Property, plant and equipment is recorded at historical cost, net of accumulated depreciation, amortization and, if applicable, impairment charges. We review our property, plant and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Depreciation is recorded over the assets' useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms. See Note 11, Property, plant and equipment.

Goodwill and other intangible assets

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recorded over the assets' estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note 12, Goodwill and other intangible assets.

The fair values of IPR&D projects acquired in a business combination that are not complete are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related R&D efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. Major risks and uncertainties are often associated with IPR&D projects because we are required to obtain regulatory approvals before marketing the resulting products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods.

Capitalized IPR&D projects are tested for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. We consider various factors for potential impairment, including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays in obtaining marketing approval, the inability to bring a product to market and the introduction or advancement of competitors' products could result in partial or full impairment of the related intangible assets.

We perform an impairment test of goodwill annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. To date, an impairment of goodwill has not been recorded. See Note 12, Goodwill and other intangible assets.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. Certain of these proceedings are discussed in Note 19, Contingencies and commitments. We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Foreign currency translation

The net assets of international subsidiaries whose functional currencies are not in U.S. dollars are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translation of the net assets of these subsidiaries at changing rates are recognized in AOCI. The subsidiaries' earnings are translated into U.S. dollars by using average exchange rates.

Equity investments

Marketable and nonmarketable equity securities

Investments in publicly traded equity securities with readily determinable fair values are recorded at quoted market prices for identical securities, with changes in fair value recorded in Other Income, net, in the Consolidated Statements of Income. Investments in equity securities without readily determinable fair values are recorded at cost minus impairment, if any, adjusted for changes resulting from observable price changes in orderly transactions for identical or similar securities. Such adjustments are recorded in Other Income, net, in the Consolidated Statements of Income.

Equity method investments

Equity investments that give us the ability to exert significant influence, but not control, over an investee for which we have not elected the fair value option are accounted for under the equity method of accounting. In concluding whether we have the ability to exercise significant influence over an investee, we consider factors such as our ownership percentage, voting and other shareholder rights, board of directors representation and the existence of other collaborative or business relationships. The equity method of accounting requires us to allocate the difference between the fair value of securities acquired and our proportionate share of the carrying value of the underlying assets (the basis difference) to various items and amortize such differences over their useful lives. Our share of investees' earnings or losses and amortization of basis differences, if any, are recorded one quarter in arrears in Other income, net, in the Consolidated Statements of Income. We record impairment losses on our equity method investments if we deem the impairment to be other-than-temporary. We deem an impairment to be other-than-temporary based on various factors, including but not limited to, the length of time the fair value is below the carrying value, volatility of the security price and our intent and ability to retain the investment to allow for a recovery in fair value.

For equity method investments for which we have elected the fair value option, changes in fair value are recorded in Other income, net, in the Consolidated Statements of Income.

Additionally, we hold investments in limited partnerships, which primarily invest in early-stage biotechnology companies. As a practical expedient, such limited partnership investments are measured by using our proportionate share of the net asset values of the underlying investments held by the limited partnerships, with such changes included in Other income, net, in the Consolidated Statements of Income.

Recent accounting pronouncements

In March 2020, the FASB issued a new accounting standard to ease the financial reporting burdens caused by the expected market transition from the LIBOR and other interbank offered rates to alternative reference rates, commonly referred to as reference rate reform. The new standard provides temporary optional expedients and exceptions to current GAAP guidance on contract modifications and hedge accounting. Specifically, a modification to transition to an alternative reference rate is treated as an event that does not require contract remeasurement or reassessment of a previous accounting treatment. Moreover, for all types of hedging relationships, an entity is permitted to change the reference rate without having to dedesignate the hedging relationship. The standard is generally effective for all contract modifications made and hedging relationships evaluated through December 31,

2022. In January 2021, the FASB issued a new accounting standard to expand the scope of the original March 2020 standard to include derivative instruments on discounting transactions. We do not expect the two standards to have a material impact on our consolidated financial statements.

In November 2021, the FASB issued a new accounting standard around the recognition and measurement of contract assets and contract liabilities from revenue contracts with customers acquired in a business combination. The new standard clarifies that contract assets and contract liabilities acquired in a business combination from an acquiree should initially be recognized by applying revenue recognition principles and not at fair value. The standard is effective for interim and annual periods beginning on January 1, 2023, and early adoption is permitted. The impact of this standard will depend on the facts and circumstances of future transactions.

2. Acquisitions

Teneobio, Inc.

On October 19, 2021, we acquired all of the outstanding stock of Teneobio, a privately held, clinical-stage biotechnology company developing a new class of biologics called human heavy-chain antibodies, which are single-chain antibodies composed of the human heavy-chain domain. The transaction, which was accounted for as a business combination, includes Teneobio's proprietary bispecific and multispecific antibody technologies, which complement Amgen's existing antibody capabilities and BiTE® platform and will enable significant acceleration and efficiency in the discovery and development of new molecules to treat diseases across Amgen's core therapeutic areas. Upon its acquisition, Teneobio became a wholly owned subsidiary of Amgen, and its operations have been included in our consolidated financial statements commencing on the acquisition date.

The following table summarizes the total consideration and allocated acquisition date fair values of assets acquired and liabilities assumed (in millions):

	Amounts
Cash purchase price	$ 994
Contingent consideration	309
Total consideration	$ 1,303
Cash and cash equivalents	$ 100
IPR&D	1,054
Finite-lived intangible asset – R&D technology rights	94
Finite-lived intangible assets – licensing rights	41
Goodwill	251
Other assets, net	16
Deferred tax liability	(253)
Total assets acquired, net	$ 1,303

The consideration for this transaction were (i) an upfront cash payment of $994 million, which included a working-capital adjustment and (ii) future contingent milestone payments to Teneobio's former equity holders of up to $1.6 billion in cash, based on the achievement of various development and regulatory milestones with regard to the leading asset (AMG 340, formerly TNB-585) and to various development milestones for other drug candidates. The estimated fair value of the contingent consideration obligations aggregated $309 million as of the acquisition date and were determined using a probability-weighted expected return methodology. The assumptions in this method include the probability of achieving the milestones and the expected payment dates, with such amounts discounted to present value based on our pre-tax cost of debt. See Note 17, Fair value measurement, for information regarding the estimated fair value of these obligations as of December 31, 2021.

The estimated fair values of acquired IPR&D assets totaled $1.1 billion, of which $784 million relates to AMG 340, that is in a phase 1 clinical trial for the treatment of mCRPC, and the balance relates to four separate preclinical oncology programs. The R&D technology rights of $94 million relate to Teneobio's proprietary bispecific and multispecific antibody technologies and will be amortized over ten years using the straight-line method. Teneobio has also licensed its technology and certain identified targets to various third parties, representing contractual agreements valued at $41 million. The estimated fair values for these intangible assets were determined using a multi-period excess earnings income approach that discounts expected future cash flows to present value by applying a discount rate that represents the estimated rate that market participants would use to value the intangible assets. The projected cash flows were based on certain assumptions attributable to the respective intangible asset, including estimates of

future revenues and expenses, the time and resources needed to complete development and the probabilities of obtaining marketing approval from the FDA and other regulatory agencies.

A deferred tax liability of $253 million was recognized on the temporary differences related to the book bases and tax bases of the acquired identifiable assets and assumed liabilities, primarily driven by the intangible assets acquired.

The excess of the acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $251 million was recorded as goodwill, which is not deductible for tax purposes. The goodwill value represents expected synergies from both AMG 340 and the technologies acquired.

Our accounting for this acquisition is preliminary and will be finalized upon completion of our analysis to determine the acquisition date fair values of certain assets acquired, liabilities assumed and tax-related items as we obtain additional information during the measurement period of up to one year from the acquisition date.

Five Prime Therapeutics, Inc.

On April 16, 2021, Amgen acquired the outstanding stock of Five Prime for total consideration of $1.6 billion, net of cash acquired. The purchase price was funded with cash on hand. This transaction was accounted for as an asset acquisition because substantially all the value of the assets acquired was concentrated in the intellectual property rights of bemarituzumab, a phase 3 trial-ready, first-in-class program for gastric cancer. The operations of Five Prime have been included in our consolidated financial statements commencing after the acquisition date.

We allocated the consideration to acquire Five Prime to the bemarituzumab IPR&D program of $1.5 billion, which was expensed immediately in Acquired IPR&D expense in the Consolidated Statements of Income; deferred tax assets of $177 million; and other net liabilities of $47 million. The acquired IPR&D expense was not tax deductible.

Otezla

On November 21, 2019, we acquired worldwide rights to Otezla, the only oral, non-biologic treatment for psoriasis and psoriatic arthritis, along with certain related assets and liabilities, from Celgene. Otezla is primarily used for the treatment of patients with moderate-to-severe plaque psoriasis for whom phototherapy or systemic therapy is appropriate and is approved in more than 50 markets outside the United States, including the European Union and Japan. The acquisition was accounted for as an asset acquisition under GAAP because substantially all of the value of the assets acquired was concentrated in the global intellectual property rights of Otezla. The operations of Otezla have been included in our consolidated financial statements commencing on the acquisition date.

The following table summarizes the consideration transferred and the allocation of the estimated accumulated cost, including tax adjustments, to the assets acquired and liabilities assumed (in millions):

	Amounts
Cash purchase price	$ 13,400
Transaction costs	40
Accumulated cost (consideration transferred)	$ 13,440
Intangible assets:	
Developed-product-technology rights	$ 13,007
Marketing-related rights	195
Inventory	367
Deferred tax liability, net	(24)
Deferred credit	(96)
Other liabilities, net	(9)
Total assets acquired, net	$ 13,440

Amgen allocated the accumulated cost of the acquisition to the assets acquired based on their relative fair values. The accumulated cost of the acquisition includes direct acquisition-related costs and applicable taxes. Goodwill is not recognized in the accounting for an asset acquisition. Rather, the excess of the accumulated cost over the fair value of the net assets acquired is reallocated to the nonfinancial assets acquired.

The developed-product-technology rights acquired relate to Otezla. The estimated fair value was determined by using a multi-period excess earnings income approach, which is based on the present value of the incremental after-tax cash flows attributable only to the intangible asset. The developed-product-technology rights is being amortized over a weighted-average period of 8.5 years by using the straight-line method.

The estimated fair value of marketing-related rights, which relate to assembled workforce, was determined using a replacement cost approach, which consists of developing an estimate of the current cost of a similar new asset having the nearest equivalent utility to the asset being valued. The assembled workforce is being amortized over a period of 5 years by using the straight-line method.

The estimated fair value of the acquired inventory was determined using the comparative sales method, which uses actual or expected selling prices of inventory as the base amount to which adjustments for selling effort and a profit on the buyer's effort are applied. Inventory fair value adjustments is being amortized as inventory turns over, which we estimate to approximate 2.5 years.

Upon closing, we had a difference between the book basis and tax basis of the assets acquired. The Company used the simultaneous equations method to determine the assigned value of the net assets acquired and the related deferred tax assets or liabilities. Use of this methodology resulted in an increase to the carrying value of the intangible assets of $119 million, a net deferred tax liability of $24 million and a deferred credit of $96 million. The tax effects of the acquisition are based on Amgen's estimated blended statutory tax rate of 20%.

Nuevolution AB

On July 15, 2019, we acquired all of the outstanding stock of Nuevolution, a publicly traded, Denmark-based biotechnology company with a leading small molecule drug discovery platform, for total consideration of $183 million in cash. The transaction, which was accounted for as a business combination, expands our ability to discover novel small molecules against difficult-to-drug targets and with greater speed and efficiency. Nuevolution's operations, which are not material, have been included in our consolidated financial statements commencing on the acquisition date.

We allocated the consideration to acquire Nuevolution to finite-lived intangible assets of $150 million, primarily comprised of technology rights for a drug discovery platform with an estimated useful life of 10 years; goodwill of $26 million, which is not tax deductible; deferred tax liabilities of $22 million; and other net assets of $29 million.

The estimated fair values of intangible assets were determined primarily by using a probability-weighted-income approach, which discounts expected future cash flows to present value by using a discount rate that represents the estimated rate that market participants would use to value the intangible assets.

3. Revenues

We operate in one business segment: human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Revenues by product and by geographic area, based on customers' locations, are presented below. The majority of ROW revenues relates to products sold in Europe.

Revenues were as follows (in millions):

	Year ended December 31, 2021			Year ended December 31, 2020			Year ended December 31, 2019		
	U.S.	ROW	Total	U.S.	ROW	Total	U.S.	ROW	Total
Enbrel	$ 4,352	$ 113	$ 4,465	$ 4,855	$ 141	$ 4,996	$ 5,050	$ 176	$ 5,226
Prolia	2,150	1,098	3,248	1,830	933	2,763	1,772	900	2,672
Otezla[1]	1,804	445	2,249	1,790	405	2,195	139	39	178
XGEVA	1,434	584	2,018	1,405	494	1,899	1,457	478	1,935
Neulasta	1,514	220	1,734	2,001	292	2,293	2,814	407	3,221
Aranesp	537	943	1,480	629	939	1,568	758	971	1,729
Repatha	557	560	1,117	459	428	887	376	285	661
KYPROLIS	736	372	1,108	710	355	1,065	654	390	1,044
Nplate	566	461	1,027	485	365	850	480	315	795
Other products	3,636	2,215	5,851	3,821	1,903	5,724	3,031	1,712	4,743
Total product sales[2]	17,286	7,011	24,297	17,985	6,255	24,240	16,531	5,673	22,204
Other revenues	908	774	1,682	511	673	1,184	693	465	1,158
Total revenues	$18,194	$ 7,785	$25,979	$18,496	$ 6,928	$25,424	$17,224	$ 6,138	$23,362

(1) Otezla was acquired on November 21, 2019.

(2) Hedging gains and losses, which are included in product sales, were not material for the years ended December 31, 2021, 2020 and 2019.

In the United States, we sell primarily to pharmaceutical wholesale distributors that we use as the principal means of distributing our products to healthcare providers. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

We had product sales to three customers, each of them accounting for more than 10% of total revenues for each of the years ended December 31, 2021, 2020 and 2019. For the year ended December 31, 2021, on a combined basis, these customers accounted for 82% of total gross revenues as shown in the following table. Certain information with respect to these customers was as follows (dollar amounts in millions):

	Years ended December 31,		
	2021	2020	2019
McKesson Corporation:			
Gross product sales	$ 15,187	$ 13,779	$ 11,795
% of total gross revenues	33 %	32 %	31 %
AmerisourceBergen Corporation:			
Gross product sales	$ 14,783	$ 14,743	$ 12,301
% of total gross revenues	32 %	34 %	33 %
Cardinal Health, Inc.:			
Gross product sales	$ 7,681	$ 7,332	$ 6,538
% of total gross revenues	17 %	17 %	17 %

As of December 31, 2021 and 2020, amounts due from these three customers each exceeded 10% of gross trade receivables and accounted for 73% and 74%, respectively, of net trade receivables on a combined basis. As of December 31, 2021 and 2020, 27% and 28%, respectively, of net trade receivables were due from customers located outside the United States, the majority of which were from Europe. Our total allowance for doubtful accounts as of December 31, 2021 and 2020, was not material.

4. Stock-based compensation

Our Amended 2009 Plan authorizes for issuance to employees of Amgen and nonemployee members of our Board of Directors shares of our common stock pursuant to grants of equity-based awards, including RSUs, stock options and performance units. The pool of shares available under the Amended 2009 Plan is reduced by one share for each stock option granted and by 1.9 shares for other types of awards granted, including full-value awards. In general, if any shares subject to an award granted under the Amended 2009 Plan expire or become forfeited, terminated or canceled without the issuance of shares, the shares subject to such awards are added back into the authorized pool on the same basis that they were removed. In addition, under the Amended 2009 Plan, shares withheld to pay for minimum statutory tax obligations with respect to full-value awards are added back into the authorized pool on the basis of 1.9 shares. As of December 31, 2021, the Amended 2009 Plan provides for future grants and/or issuances of up to approximately 19 million shares of our common stock. Stock-based awards under our employee compensation plans are made with newly issued shares reserved for this purpose.

The following table reflects the components of stock-based compensation expense recognized in our Consolidated Statements of Income (in millions):

	Years ended December 31,		
	2021	2020	2019
RSUs	$ 183	$ 178	$ 168
Performance units	121	118	105
Stock options	37	34	35
Total stock-based compensation expense, pretax	341	330	308
Tax benefit from stock-based compensation expense	(74)	(72)	(67)
Total stock-based compensation expense, net of tax	$ 267	$ 258	$ 241

Restricted stock units and stock options

Eligible employees generally receive an annual grant of RSUs and, for certain executive-level employees, stock options, with the size and type of award generally determined by the employee's salary grade and performance level. Certain management and professional-level employees typically receive RSU grants upon commencement of employment. Nonemployee members of our Board of Directors also receive an annual grant of RSUs.

Our RSU and stock option grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including upon death, disability, termination in connection with a change in control and the retirement of employees who meet certain service and/or age requirements. RSUs and stock options generally vest in equal amounts on the second, third and fourth anniversaries of the grant date. RSUs accrue dividend equivalents, which are typically payable in shares only when and to the extent the underlying RSUs vest and are issued to the recipient.

Restricted stock units

The grant date fair value of an RSU equals the closing price of our common stock on the grant date, as RSUs accrue dividend equivalents during their vesting period. The weighted-average grant date fair values per unit of RSUs granted during the years ended December 31, 2021, 2020 and 2019, were $233.10, $235.63 and $182.12, respectively.

The following table summarizes information regarding our RSUs:

	Year ended December 31, 2021	
	Units (in millions)	Weighted-average grant date fair value
Balance nonvested as of December 31, 2020	3.0	$ 198.11
Granted	1.3	$ 233.10
Vested	(0.9)	$ 177.27
Forfeited	(0.4)	$ 213.32
Balance nonvested as of December 31, 2021	3.0	$ 217.95

The total grant date fair values of RSUs that vested during the years ended December 31, 2021, 2020 and 2019, were $166 million, $161 million and $160 million, respectively.

Stock options

The exercise price of stock options is set as the closing price of our common stock on the grant date, and the related number of shares granted is fixed at that point in time. Awards expire 10 years from the date of grant. We use the Black–Scholes option valuation model to estimate the grant date fair value of stock options.

The weighted-average assumptions used in the option valuation model and the resulting weighted-average grant date fair values of stock options granted were as follows:

	Years ended December 31,		
	2021	2020	2019
Closing price of our common stock on grant date	$ 237.17	$ 236.36	$ 177.31
Expected volatility (average of implied and historical volatility)	25.6 %	28.1 %	23.5 %
Expected life (in years)	5.7	5.8	5.8
Risk-free interest rate	1.0 %	0.4 %	2.4 %
Expected dividend yield	2.9 %	3.0 %	3.1 %
Fair value of stock options granted	$ 40.43	$ 42.34	$ 30.47

The following table summarizes information regarding our stock options:

	Year ended December 31, 2021			
	Options (in millions)	Weighted-average exercise price	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in millions)
Balance unexercised as of December 31, 2020	4.7	$ 179.90		
Granted	1.3	$ 237.17		
Exercised	(0.5)	$ 137.95		
Expired/forfeited	(0.4)	$ 208.56		
Balance unexercised as of December 31, 2021	5.1	$ 197.27	7.3	$ 168
Vested or expected to vest as of December 31, 2021	4.9	$ 195.64	7.2	$ 167
Exercisable as of December 31, 2021	2.0	$ 165.46	5.6	$ 120

The total intrinsic values of options exercised during the years ended December 31, 2021, 2020 and 2019, were $56 million, $98 million and $68 million, respectively. The actual tax benefits realized from tax deductions from

option exercises during the years ended December 31, 2021, 2020 and 2019, were $12 million, $21 million and $15 million, respectively.

As of December 31, 2021, $346 million of unrecognized compensation cost was related to nonvested RSUs and unvested stock options, which is expected to be recognized over a weighted-average period of 1.8 years.

Performance units

Certain management-level employees also receive annual grants of performance units, which give the recipient the right to receive common stock that is contingent upon achievement of specified preestablished goals over the performance period, which is generally three years. The performance goals for the units granted during the years ended December 31, 2021, 2020 and 2019, which are accounted for as equity awards, are based on (i) Amgen's stockholder return compared with a comparator group of companies, which are considered market conditions and are therefore reflected in the grant date fair values of the units, and (ii) Amgen's stand-alone financial performance measures, which are considered performance conditions. The expense recognized for awards is based on the grant date fair value of a unit multiplied by the number of units expected to be earned with respect to the related performance conditions, net of estimated forfeitures. Depending on the outcome of these performance goals, a recipient may ultimately earn a number of units greater or less than the number of units granted. Shares of our common stock are issued on a one-for-one basis for each performance unit earned. In general, performance unit awards vest at the end of the performance period. The performance award program provides for accelerated or continued vesting in certain circumstances as defined in the plan, including upon death, disability, a change in control and retirement of employees who meet certain service and/or age requirements. Performance units accrue dividend equivalents that are typically payable in shares only when and to the extent the underlying performance units vest and are issued to the recipient, including with respect to market and performance conditions that affect the number of performance units earned.

We use a payout simulation model to estimate the grant date fair value of performance units. The weighted-average assumptions used in the payout simulation model and the resulting weighted-average grant date fair values of performance units granted were as follows:

	Years ended December 31,		
	2021	2020	2019
Closing price of our common stock on grant date	$ 239.64	$ 236.36	$ 177.31
Volatility	29.3 %	27.5 %	22.1 %
Risk-free interest rate	0.3 %	0.2 %	2.3 %
Fair value of units granted	$ 254.68	$ 249.07	$ 188.40

The payout simulation model assumes correlations of returns of the stock prices of our common stock and the common stocks of the comparator groups of companies and stock price volatilities of the comparator groups of companies to simulate stockholder returns over the performance periods and their resulting impact on the payout percentages based on the contractual terms of the performance units.

As of December 31, 2021 and 2020, 1.6 million and 1.8 million performance units were outstanding, with weighted-average grant date fair values per unit of $229.39 and $207.52 per unit, respectively. During the year ended December 31, 2021, 0.6 million performance units with a weighted-average grant date fair value per unit of $254.68 were granted, and 0.2 million performance units with a weighted-average grant date fair value per unit of $226.32 were forfeited.

The total fair values of performance units paid during the years ended December 31, 2021, 2020 and 2019, were $149 million, $230 million and $176 million, respectively, based on the number of performance units earned multiplied by the closing stock price of our common stock on the last day of the performance period.

As of December 31, 2021, $130 million of unrecognized compensation cost was related to nonvested performance units, which is expected to be recognized over a weighted-average period of one year.

5. Defined contribution plan

The Company has defined contribution plans to which certain employees of the Company and participating subsidiaries may defer compensation for income tax purposes. Participants are eligible to receive matching contributions based on their contributions, in addition to other Company contributions. Defined contribution plan expenses were $279 million, $231 million and $220 million for the years ended December 31, 2021, 2020 and 2019, respectively.

6. Income taxes

Income before income taxes included the following (in millions):

	Years ended December 31,		
	2021	2020	2019
Domestic	$ 1,850	$ 4,087	$ 4,371
Foreign	4,851	4,046	4,767
Total income before income taxes	$ 6,701	$ 8,133	$ 9,138

The provision for income taxes included the following (in millions):

	Years ended December 31,		
	2021	2020	2019
Current provision:			
Federal	$ 865	$ 921	$ 1,284
State	18	34	39
Foreign	359	277	277
Total current provision	1,242	1,232	1,600
Deferred benefit:			
Federal	(308)	(321)	(276)
State	(9)	9	(22)
Foreign	(117)	(51)	(6)
Total deferred benefit	(434)	(363)	(304)
Total provision for income taxes	$ 808	$ 869	$ 1,296

Deferred income taxes reflect the tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards and the tax effects of NOL carryforwards. Significant components of our deferred tax assets and liabilities were as follows (in millions):

	December 31,	
	2021	2020
Deferred income tax assets:		
NOL and credit carryforwards	$ 1,065	$ 794
Accrued expenses	600	561
Expenses capitalized for tax	244	144
Stock-based compensation	96	92
Other	326	301
Total deferred income tax assets	2,331	1,892
Valuation allowance	(663)	(571)
Net deferred income tax assets	1,668	1,321
Deferred income tax liabilities:		
Acquired intangible assets	(824)	(903)
Debt	(275)	(282)
Fixed assets	(129)	(148)
Other	(221)	(189)
Total deferred income tax liabilities	(1,449)	(1,522)
Total deferred income taxes, net	$ 219	$ (201)

Valuation allowances are provided to reduce the amounts of our deferred tax assets to an amount that is more likely than not to be realized based on an assessment of positive and negative evidence, including estimates of future taxable income necessary to realize future deductible amounts.

The valuation allowance increased in 2021, primarily driven by the Company's expectation that some state R&D credits will not be utilized and certain foreign and acquired net operating losses will expire unused.

As of December 31, 2021, we had $75 million of federal tax credit carryforwards available to reduce future federal income taxes and have provided no valuation allowance for those federal tax credit carryforwards. The federal tax credit carryforwards expire between 2023 and 2040. We had $798 million of state tax credit carryforwards available to reduce future state income taxes and have provided a valuation allowance for $709 million of those state tax credit carryforwards.

As of December 31, 2021, we had $606 million of federal NOL carryforwards available to reduce future federal income taxes and have provided a valuation allowance for $6 million of those federal NOL carryforwards. For the federal NOL carryforwards for which no valuation allowance has been provided, $426 million have no expiration; the remainder begin to expire between 2022 and 2037. We had $391 million of state NOL carryforwards available to reduce future state income taxes and have provided a valuation allowance for $330 million of those state NOL carryforwards. We had $2.0 billion of foreign NOL carryforwards available to reduce future foreign income taxes and have provided a valuation allowance for $561 million of those foreign NOL carryforwards. For the foreign NOLs with no valuation allowance provided, $800 million has no expiry; and the remainder will expire between 2022 and 2031.

The reconciliations of the total gross amounts of UTBs were as follows (in millions):

	Years ended December 31,		
	2021	2020	2019
Beginning balance	$ 3,352	$ 3,287	$ 3,061
Additions based on tax positions related to the current year	171	165	215
Additions based on tax positions related to prior years	35	3	22
Reductions for tax positions of prior years	(4)	(35)	(11)
Settlements	(8)	(68)	—
Ending balance	$ 3,546	$ 3,352	$ 3,287

Substantially all of the UTBs as of December 31, 2021, if recognized, would affect our effective tax rate. During the year ended December 31, 2020, we effectively settled certain issues with the IRS. As a result, we remeasured our UTBs accordingly.

Interest and penalties related to UTBs are included in our provision for income taxes. During the years ended December 31, 2021, 2020 and 2019, we recognized $98 million, $116 million and $198 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. The decrease in interest expense for the year ended December 31, 2021, was primarily due to lower interest rates during 2021 and settlement of a prior year audit. As of December 31, 2021 and 2020, accrued interest and penalties associated with UTBs were $881 million and $783 million, respectively.

The reconciliations between the federal statutory tax rate applied to income before income taxes and our effective tax rate were as follows:

	Years ended December 31,		
	2021	2020	2019
Federal statutory tax rate	21.0 %	21.0 %	21.0 %
Foreign earnings	(7.8)%	(4.7)%	(4.5)%
Foreign-derived intangible income	(1.0)%	(0.7)%	(0.7)%
Credits, Puerto Rico excise tax	(3.4)%	(2.9)%	(2.6)%
Interest on uncertain tax positions	1.1 %	1.1 %	1.6 %
Credits, primarily federal R&D	(2.1)%	(1.4)%	(1.0)%
Acquisition IPR&D	4.9 %	— %	— %
Audit settlements	— %	(1.0)%	— %
Other, net	(0.6)%	(0.7)%	0.4 %
Effective tax rate	12.1 %	10.7 %	14.2 %

The effective tax rates for the years ended December 31, 2021, 2020 and 2019, differ from the federal statutory rate primarily due to impacts of the jurisdictional mix of income and expenses. Substantially all of the benefit to our effective tax rate from foreign earnings results from the Company's operations in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes. Our operations in Puerto Rico are subject to tax incentive grants through 2035. Additionally, the Company's operations conducted in Singapore are subject to a tax incentive grant through 2034. Our foreign earnings are also subject to U.S. tax at a reduced rate of 10.5%.

The U.S. territory of Puerto Rico imposes an excise tax on the gross intercompany purchase price of goods and services from our manufacturing site in Puerto Rico. The rate of 4% is effective through December 31, 2027. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in Cost of sales when the related products are sold. For U.S. income tax purposes in 2021, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes when the excise tax is incurred.

Income taxes paid during the years ended December 31, 2021, 2020 and 2019, were $1.9 billion, $1.4 billion and $1.9 billion, respectively.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes may arise with tax authorities involving issues regarding the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and relevant facts. Tax authorities (including the IRS) are becoming more aggressive and are particularly focused on such matters.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010, 2011 and 2012 proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS appeals office but were unable to reach resolution. In July 2021, we filed a petition in the U.S. Tax Court to contest two duplicate Notices for 2010, 2011 and 2012 that we received in May and July 2021, which seek to increase our U.S. taxable income. The Notices seek to increase our U.S. taxable income by an amount that would result in additional federal tax of approximately $3.6 billion plus interest. Any additional tax that could be imposed would be reduced by up to approximately $900 million of repatriation tax previously accrued on our foreign earnings. We firmly believe that the IRS's positions set forth in the Notices are without merit, and we are contesting the Notices through the judicial process.

In 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015, also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS appeals office. We were unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a statutory notice of deficiency for these years as well. We expect to contest any such notice related to 2013–15 through the

judicial process. We are also currently under examination by the IRS for the years 2016, 2017 and 2018 and by a number of state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our consolidated financial statements.

We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009.

7. Earnings per share

The computation of basic EPS is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which primarily include shares that may be issued under our stock option, restricted stock and performance unit award programs (collectively, dilutive securities), as determined by using the treasury stock method.

The computations for basic and diluted EPS were as follows (in millions, except per-share data):

	Years ended December 31,		
	2021	2020	2019
Income (Numerator):			
Net income for basic and diluted EPS	$ 5,893	$ 7,264	$ 7,842
Shares (Denominator):			
Weighted-average shares for basic EPS	570	586	605
Effect of dilutive securities	3	4	4
Weighted-average shares for diluted EPS	573	590	609
Basic EPS	$ 10.34	$ 12.40	$ 12.96
Diluted EPS	$ 10.28	$ 12.31	$ 12.88

For each of the three years ended December 31, 2021, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

8. Collaborations

A collaborative arrangement is a contractual arrangement that involves a joint operating activity. Such arrangements involve two or more parties that are both (i) active participants in the activity and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for nonrefundable upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration arrangements are performed with no guarantee of either technological or commercial success, and each arrangement is unique in nature. See Note 1, Summary of significant accounting policies, for additional discussion of revenues recognized under these types of arrangements. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line items in the Consolidated Statements of Income, net of any payments due to or reimbursements due from our collaboration partners, with such reimbursements being recognized at the time the party becomes obligated to pay. Our significant arrangements are discussed below.

On January 2, 2020, we acquired a 20.5% stake in BeiGene for approximately $2.8 billion in cash as part of a collaboration to expand our oncology presence in China. For additional information regarding our equity investment in BeiGene, see Note 9, Investments. Under the collaboration, BeiGene began selling XGEVA in 2020, BLINCYTO in 2021 and KYPROLIS in early 2022 in China, and Amgen shares profits and losses equally during the initial product-specific commercialization periods; thereafter, product rights may revert to Amgen, and Amgen will pay royalties to BeiGene on sales in China of such products for a specified period.

In addition, we jointly develop a portion of our oncology portfolio with BeiGene, which shares in global R&D costs by providing cash and development services of up to $1.25 billion. Upon regulatory approval, BeiGene will assume commercialization rights in China for a specified period, and Amgen and BeiGene will share profits equally until certain of these product rights revert to Amgen. Upon return of the product rights, Amgen will pay royalties to BeiGene on sales in China for a specified period. For product sales outside China, Amgen will also pay royalties to BeiGene.

During the years ended December 31, 2021 and 2020, net costs recovered from BeiGene for oncology product candidates were $220 million and $225 million, respectively, and were recorded as an offset to R&D expense in the Consolidated Statements of Income. During the year ended December 31, 2021, product sales from Amgen to BeiGene under the collaboration were $72 million and were recorded in Product sales in the Consolidated Statements of Income. During the year ended December 31, 2021, profit and loss share expenses related to the initial product-specific commercialization period were $64 million and were recorded primarily in SG&A expense in the Consolidated Statements of Income. Product sales from Amgen to BeiGene and profit and loss share expenses were not material during the year ended December 31, 2020. Amounts owed from BeiGene for product sales were $21 million and $22 million as of December 31, 2021 and 2020, respectively, which are included in Trade receivables, net, in the Consolidated Balance Sheets. Net amounts owed from BeiGene for cost recoveries and profit and loss share payments were $61 million and $99 million as of December 31, 2021 and 2020, respectively, which are included in Other current assets in the Consolidated Balance Sheets.

Novartis Pharma AG

We are in a collaboration with Novartis to jointly develop and commercialize Aimovig. On January 31, 2022, concurrent with the settlement of the previously disclosed litigation between Amgen and Novartis we modified the terms of the collaboration. See Note 19, Contingencies and commitments.

Arrangement through December 31, 2021

In the United States, Amgen and Novartis jointly developed and collaborated on the commercialization of Aimovig. Amgen, as the principal, recognized product sales of Aimovig in the United States, shared U.S. commercialization costs with Novartis and paid Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig (the ex-U.S. Novartis Rights). Novartis paid Amgen double-digit royalties on net sales of the product in the ex-U.S. Novartis Rights territories and funded a portion of global R&D expenses. In addition, Novartis was required to make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds were achieved with respect to Aimovig in the United States.

Arrangement after January 1, 2022

Pursuant to the amendment effective January 1, 2022, Novartis retains the ex-U.S. Novartis Rights and will continue to pay double-digit royalties on net sales in the ex-U.S. Novartis Rights territories. In the United States, Novartis will no longer collaborate with Amgen, share Aimovig commercialization costs or pay milestones and Amgen will no longer pay royalties to Novartis on sales of Aimovig. Amgen and Novartis will continue to share development expenses worldwide. In the United States, Novartis will no longer collaborate with Amgen or share Aimovig commercialization costs and Amgen will no longer pay royalties to Novartis on sales of Aimovig. Amgen and Novartis will continue to share development expenses worldwide.

Amgen manufactures and supplies Aimovig worldwide.

During the years ended December 31, 2021, 2020 and 2019, net costs recovered from Novartis for migraine products were $160 million, $192 million and $187 million, respectively, and were recorded primarily in SG&A expense in the Consolidated Statements of Income. During the years ended December 31, 2021, 2020 and 2019, royalties due to Novartis for Aimovig were $116 million, $139 million and $115 million, respectively, and were recorded in Cost of sales in the Consolidated Statements of Income. During the years ended December 31, 2021, 2020 and 2019, royalties due from Novartis for Aimovig were not material.

Kyowa Kirin Co., Ltd.

On July 30, 2021, we closed our collaboration and licensing agreement with KKC to jointly develop and commercialize an anti-OX40 fully human monoclonal antibody (AMG 451) worldwide, except in Japan. AMG 451 is for the treatment of atopic dermatitis, with potential for treatment of other autoimmune diseases.

Under the terms of the agreement, we will lead the global development, manufacture and commercialization of AMG 451, except in Japan. KKC will co-promote AMG 451 with Amgen in the United States and have opt-in rights to co-promote AMG 451 in various other markets outside the United States, including in Europe and Asia.

We made an upfront payment of $400 million to KKC that was recognized in R&D expense in the third quarter of 2021. Amgen and KKC will share equally the global development costs, except in Japan, and the U.S. commercialization costs. Outside the United States and Japan, any commercialization costs incurred by KKC will be reimbursed by Amgen. We may also be required to make milestone payments of up to $850 million contingent upon the achievement of certain regulatory events and commercial thresholds. We will also pay KKC significant double-digit royalties on global sales, except in Japan. Net costs due to KKC were not material during the year ended December 31, 2021.

Other

In addition to the collaborations discussed above, we have various other collaborations that are not individually significant to our business at this time. Pursuant to the terms of those agreements, we may be required to pay additional amounts or we may receive additional amounts upon the achievement of various development and commercial milestones that in the aggregate could be significant. We may also incur or have reimbursed to us significant R&D costs if a related product candidate were to advance to late-stage clinical trials. In addition, if any products related to these collaborations are approved for sale, we may be required to pay significant royalties or we may receive significant royalties on future sales. The payments of these amounts, however, are contingent upon the occurrence of various future events that have high degrees of uncertainty of occurrence.

9. Investments

Available-for-sale investments

The amortized cost, gross unrealized gains, gross unrealized losses and fair values of interest-bearing securities, all of which are considered available-for-sale, by type of security were as follows (in millions):

Types of securities as of December 31, 2021	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 47	$ —	$ —	$ 47
U.S. Treasury bills	1,400	—	—	1,400
Money market mutual funds	5,856	—	—	5,856
Other short-term interest-bearing securities	1	—	—	1
Total available-for-sale investments	$ 7,304	$ —	$ —	$ 7,304

Types of securities as of December 31, 2020	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 129	$ 1	$ —	$ 130
U.S. Treasury bills	4,948	—	—	4,948
Money market mutual funds	4,765	—	—	4,765
Other short-term interest-bearing securities	2	—	—	2
Total available-for-sale investments	$ 9,844	$ 1	$ —	$ 9,845

The fair values of available-for-sale investments by location in the Consolidated Balance Sheets were as follows (in millions):

	December 31,	
Consolidated Balance Sheets locations	2021	2020
Cash and cash equivalents	$ 7,256	$ 5,464
Marketable securities	48	4,381
Total available-for-sale investments	$ 7,304	$ 9,845

Cash and cash equivalents in the above table excludes bank account cash of $733 million and $802 million as of December 31, 2021 and 2020, respectively.

The fair values of available-for-sale investments by contractual maturity were as follows (in millions):

Contractual maturities	December 31, 2021	December 31, 2020
Maturing in one year or less	$ 7,304	$ 9,795
Maturing after one year through three years	—	50
Total available-for-sale investments	$ 7,304	$ 9,845

For the years ended December 31, 2021 and 2020, realized gains and losses on interest-bearing securities were not material. For the year ended December 31, 2019, realized gains on interest-bearing securities were $92 million and realized losses were not material. Realized gains and losses on interest-bearing securities are recorded in Other income, net, in the Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

The primary objective of our investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

Equity securities

We held investments in equity securities with readily determinable fair values of $611 million and $477 million as of December 31, 2021 and 2020, respectively, which are included in Other noncurrent assets in the Consolidated Balance Sheets. For the years ended December 31, 2021, 2020 and 2019, net unrealized gains on publicly traded securities were $161 million, $174 million and $112 million, respectively. Realized gains and losses on publicly traded securities for the years ended December 31, 2021, 2020 and 2019, were not material.

We held investments of $262 million and $203 million in equity securities without readily determinable fair values as of December 31, 2021 and 2020, respectively, which are included in Other noncurrent assets in the Consolidated Balance Sheets. For the year ended December 31, 2021, gains due to upward adjustments on these securities were $152 million, and gains realized on the dispositions of these securities were $41 million; for the years ended December 31, 2020 and 2019, gains due to upward adjustments and gains realized upon dispositions of these securities were not material. For the years ended December 31, 2021, 2020 and 2019, downward adjustments to the carrying values of these securities were not material. Adjustments were based on observable price transactions.

Equity Method Investments

BeiGene, Ltd.

On January 2, 2020, we acquired a 20.5% ownership interest in BeiGene for $2.8 billion, of which $2.6 billion was attributed to the fair value of equity securities upon closing, with the remainder attributed to prepaid R&D. Our equity investment in BeiGene is included in Other noncurrent assets in the Consolidated Balance Sheets. Our equity investment is accounted for under the equity method of accounting due to our ability to exert significant influence over BeiGene. See Note 1, Summary of significant accounting policies, for factors in concluding our ability to exert significant influence over BeiGene. The fair value of equity securities acquired exceeded our proportionate share of the carrying value of the underlying net assets of BeiGene by approximately $2.4 billion. The equity method of accounting requires us to identify and allocate amounts to items that give rise to the basis difference and to amortize these items over their useful lives. This amortization, along with our share of the results of operations of BeiGene, is included in Other income, net, in our Consolidated Statements of Income. Recognition occurs one quarter in arrears, which began in the second quarter of 2020. The basis difference was allocated to finite-lived intangible assets, indefinite-lived intangible assets, equity-method goodwill and related deferred taxes. The finite-lived intangible assets are being amortized over a period ranging from 8 to 15 years.

During the years ended December 31, 2021 and 2020, the carrying value of the investment was reduced by our share of BeiGene's net losses of $265 million and $229 million, respectively, and amortization of the basis difference of $172 million and $109 million, respectively. During the years ended December 31, 2021 and 2020, we increased the carrying value by $50 million and $569 million, respectively, as a result of our purchase of additional shares of BeiGene. In addition, during the years ended December 31, 2021 and 2020, the carrying value increased by $265 million and $34 million, respectively, from the impact of other BeiGene ownership transactions.

As of December 31, 2021 and 2020, our ownership interest in BeiGene was approximately 18.4% and 20.5%, respectively. As of December 31, 2021 and 2020, the carrying value of our investment in BeiGene was $2.8 billion and $2.9 billion, respectively. As of December 31, 2021 and 2020, the fair value of our investment in BeiGene was $5.1 billion and $4.9 billion, respectively. We believe that as of December 31, 2021, the carrying value of our equity investment in BeiGene is fully recoverable. For information on a collaboration agreement we entered into with BeiGene in connection with this investment, see Note 8, Collaborations.

Neumora Therapeutics, Inc.

On September 30, 2021, we acquired an approximately 25.9% ownership interest in Neumora, a privately held company, for $257 million, which is included in Other noncurrent assets in the Consolidated Balance Sheets, in exchange for a $100 million cash payment and $157 million in noncash consideration primarily related to future services. Although our equity investment provides us with the ability to exercise significant influence over Neumora, we have elected the fair value option to account for our equity investment. Under the fair value option, changes in the fair value of the investment are recognized through earnings each reporting period. We believe the fair value option best reflects the economics of the underlying transaction. As of December 31, 2021, our ownership interest in Neumora remained at approximately 25.9%, and the fair value of our investment was $220 million. Accordingly, during the fourth quarter of 2021, we recognized a loss of $37 million for the reduction in the fair value in Other income, net, in the Consolidated Statements of Income. For information on determination of fair values, see Note 17, Fair value measurement.

Limited partnerships

We held limited partnership investments of $573 million and $496 million as of December 31, 2021 and 2020, respectively, which are included in Other noncurrent assets in the Consolidated Balance Sheets. These investments, which are primarily investment funds of early-stage biotechnology companies, are accounted for by using the equity method of accounting and are measured by using our proportionate share of the net asset values of the underlying investments held by the limited partnerships as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of December 31, 2021, unfunded additional commitments to be made for these investments during the next several years were $185 million. For the years ended December 31, 2021, 2020 and 2019, net gains recognized from our limited partnership investments were $143 million, $241 million and $27 million, respectively.

10. Inventories

Inventories consisted of the following (in millions):

	December 31,	
	2021	2020
Raw materials	$ 647	$ 486
Work in process	2,367	2,437
Finished goods	1,072	970
Total inventories	$ 4,086	$ 3,893

11. Property, plant and equipment

Property, plant and equipment consisted of the following (dollar amounts in millions):

		December 31,	
	Useful life (in years)	2021	2020
Land	—	$ 279	$ 259
Buildings and improvements	10-40	4,028	3,857
Manufacturing equipment	8-12	3,080	2,865
Laboratory equipment	8-12	1,193	1,257
Fixed equipment	12	2,402	2,406
Capitalized software	3-5	1,151	1,216
Other	5-10	862	1,091
Construction in progress	—	987	915
Property, plant and equipment, gross		13,982	13,866
Less accumulated depreciation and amortization		(8,798)	(8,977)
Property, plant and equipment, net		$ 5,184	$ 4,889

During the years ended December 31, 2021, 2020 and 2019, we recognized depreciation and amortization expense associated with our property, plant and equipment of $644 million, $640 million and $635 million, respectively.

Geographic information

Certain geographic information with respect to property, plant and equipment, net (long-lived assets), was as follows (in millions):

	December 31,	
	2021	2020
United States	$ 2,801	$ 2,473
Puerto Rico	1,311	1,331
ROW	1,072	1,085
Total property, plant and equipment, net	$ 5,184	$ 4,889

12. Goodwill and other intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows (in millions):

	December 31,	
	2021	2020
Beginning balance	$ 14,689	$ 14,703
Addition from acquisitions	251	—
Currency translation adjustments	(50)	(14)
Ending balance	$ 14,890	$ 14,689

Other intangible assets

Other intangible assets consisted of the following (in millions):

	December 31,					
	2021			2020		
	Gross carrying amounts	Accumulated amortization	Other intangible assets, net	Gross carrying amounts	Accumulated amortization	Other intangible assets, net
Finite-lived intangible assets:						
Developed-product-technology rights	$ 25,561	$ (12,769)	$ 12,792	$ 25,591	$ (10,564)	$ 15,027
Licensing rights	3,807	(2,973)	834	3,743	(2,791)	952
Marketing-related rights	1,354	(1,112)	242	1,367	(1,041)	326
R&D technology rights	1,377	(1,133)	244	1,317	(1,065)	252
Total finite-lived intangible assets	32,099	(17,987)	14,112	32,018	(15,461)	16,557
Indefinite-lived intangible assets:						
IPR&D	1,070	—	1,070	30	—	30
Total other intangible assets	$ 33,169	$ (17,987)	$ 15,182	$ 32,048	$ (15,461)	$ 16,587

Developed-product-technology rights consists of rights related to marketed products acquired in acquisitions. Licensing rights consists primarily of contractual rights acquired in acquisitions to receive future milestone, royalty and profit-sharing payments; capitalized payments to third parties for milestones related to regulatory approvals to commercialize products; and up-front payments associated with royalty obligations for marketed products. Marketing-related rights consists primarily of rights related to the sale and distribution of marketed products. R&D technology rights pertains to technologies used in R&D that have alternative future uses.

IPR&D consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. All IPR&D projects have major risks and uncertainties associated with the timely and successful completion of the development and commercialization of product candidates, including our ability to confirm safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not permitted to market a human therapeutic without obtaining regulatory approvals, and such approvals require the completion of clinical trials that demonstrate that a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans as well as competitive product launches, affect the revenues a product can generate. Consequently, the eventual realized values, if any, of acquired IPR&D projects may vary from their estimated fair values. We review IPR&D projects for impairment annually, whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable and upon the establishment of technological feasibility or regulatory approval.

During the year ended December 31, 2021, we acquired certain finite-lived and indefinite-lived intangible assets as a result of the Teneobio acquisition, including IPR&D of $1.1 billion, R&D technology rights of $94 million and licensing rights of $41 million. See Note 2, Acquisitions.

During the years ended December 31, 2021, 2020 and 2019, we recognized amortization associated with our finite-lived intangible assets of $2.6 billion, $2.8 billion and $1.4 billion, respectively. Amortization of intangible assets is included primarily in Cost of sales in the Consolidated Statements of Income. The total estimated amortization for our finite-lived intangible assets for the years ending December 31, 2022, 2023, 2024, 2025 and 2026, are $2.5 billion, $2.5 billion, $2.4 billion, $2.2 billion and $1.8 billion, respectively.

13. Leases

We lease certain facilities and equipment related primarily to administrative, R&D and sales and marketing activities. Leases with terms of 12 months or less are expensed on a straight-line basis over the term and are not recorded in the Consolidated Balance Sheets.

Most leases include one or more options to renew, with renewal terms that may extend the lease term up to seven years. The exercise of lease renewal options is at our sole discretion. In addition, some of our lease agreements include rental payments adjusted periodically for inflation. Our lease agreements neither contain residual value guarantees nor impose significant restrictions or covenants. We sublease certain real estate to third parties. Our sublease portfolio consists of operating leases from former R&D and administrative space.

The following table summarizes information related to our leases, all of which are classified as operating, included in our Consolidated Balance Sheets (in millions):

	December 31,	
Consolidated Balance Sheets locations	**2021**	**2020**
Assets:		
Other noncurrent assets	$ 566	$ 408
Liabilities:		
Accrued liabilities	$ 145	$ 153
Other noncurrent liabilities	525	306
Total lease liabilities	$ 670	$ 459

The components of net lease costs were as follows (in millions):

	Years ended December 31,		
Lease costs	**2021**	**2020**	**2019**
Operating[1]	$ 237	$ 223	$ 204
Sublease income	(38)	(34)	(33)
Total net lease costs	$ 199	$ 189	$ 171

[1] Includes short-term leases and variable lease costs, which were not material for the years ended December 31, 2021, 2020 and 2019.

Maturities of lease liabilities as of December 31, 2021, were as follows (in millions):

Maturity dates	**Amounts**
2022	$ 148
2023	148
2024	75
2025	49
2026	44
Thereafter	289
Total lease payments[1]	753
Less imputed interest	(83)
Present value of lease liabilities	$ 670

[1] Includes future rental commitments for abandoned leases of $138 million. We expect to receive total future rental income of $108 million related to noncancelable subleases for abandoned facilities.

The weighted-average remaining lease terms and weighted-average discount rates were as follows:

	December 31,	
	2021	2020
Weighted-average remaining lease term (in years)	8.3	3.7
Weighted-average discount rate	2.5 %	3.1 %

Cash and noncash information related to our leases was as follows (in millions):

	Years ended December 31,		
	2021	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows for operating leases	$ 190	$ 177	$ 148
ROU assets obtained in exchange for lease obligations:			
Operating leases	$ 340	$ 101	$ 163

As of December 31, 2021, we have entered into leases that have not yet commenced, with total undiscounted future lease payments of $35 million. These leases will commence in 2022 with lease terms from 4 to 6 years.

14. Other current assets and accrued liabilities

Other current assets consisted of the following (in millions):

	December 31,	
	2021	2020
Prepaid expenses	$ 1,223	$ 1,156
Corporate partner receivables	780	583
Tax receivables	164	216
Other	200	124
Total other current assets	$ 2,367	$ 2,079

Accrued liabilities consisted of the following (in millions):

	December 31,	
	2021	2020
Sales deductions	$ 5,174	$ 4,801
Dividends payable	1,083	1,018
Employee compensation and benefits	1,081	1,098
Income taxes payable	701	828
Sales returns reserve	542	474
Other	2,150	1,922
Total accrued liabilities	$ 10,731	$ 10,141

15. Financing arrangements

Our borrowings consisted of the following (in millions):

	December 31,	
	2021	2020
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	—	1,527
2.70% notes due 2022 (2.70% 2022 Notes)	—	500
2.65% notes due 2022 (2.65% 2022 Notes)	—	1,500
3.625% notes due 2022 (3.625% 2022 Notes)	—	750
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	767	791
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
1.90% notes due 2025 (1.90% 2025 Notes)	500	500
3.125% notes due 2025 (3.125% 2025 Notes)	1,000	1,000
2.00% €750 million notes due 2026 (2.00% 2026 euro Notes)	853	916
2.60% notes due 2026 (2.60% 2026 Notes)	1,250	1,250
5.50% £475 million notes due 2026 (5.50% 2026 pound sterling Notes)	643	649
2.20% notes due 2027 (2.20% 2027 Notes)	1,750	1,750
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
1.65% notes due in 2028 (1.65% 2028 Notes)	1,250	—
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	947	957
2.45% notes due 2030 (2.45% 2030 Notes)	1,250	1,250
2.30% notes due 2031 (2.30% 2031 Notes)	1,250	1,250
2.00% notes due 2032 (2.00% 2032 Notes)	1,250	—
6.375% notes due 2037 (6.375% 2037 Notes)	478	478
6.90% notes due 2038 (6.90% 2038 Notes)	254	254
6.40% notes due 2039 (6.40% 2039 Notes)	333	333
3.15% notes due 2040 (3.15% 2040 Notes)	2,000	2,000
5.75% notes due 2040 (5.75% 2040 Notes)	373	373
2.80% notes due 2041 (2.80% 2041 Notes)	1,150	—
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	729	729
5.65% notes due 2042 (5.65% 2042 Notes)	415	415
5.375% notes due 2043 (5.375% 2043 Notes)	185	185
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415
3.375% notes due 2050 (3.375% 2050 Notes)	2,250	2,250
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
3.00% notes due 2052 (3.00% 2052 Notes)	1,350	—
2.77% notes due 2053 (2.77% 2053 Notes)	940	940
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(1,213)	(1,188)
Fair value adjustments	284	566
Other	15	5
Total carrying value of debt	33,309	32,986
Less current portion	(87)	(91)
Total long-term debt	$ 33,222	$ 32,895

There are no material differences between the effective interest rates and the coupon rates of any of our borrowings, except for the 4.563% 2048 Notes, the 4.663% 2051 Notes and the 2.77% 2053 Notes, which have effective interest rates of 6.3%, 5.6% and 5.2%, respectively.

Under the terms of all of our outstanding notes, except our Other notes due 2097, in the event of a change-in-control triggering event we may be required to purchase all or a portion of these debt securities at prices equal to 101% of the principal amounts of the notes plus accrued and unpaid interest. In addition, all of our outstanding notes —except our 0.41% 2023 Swiss franc Bonds and Other notes due 2097—may be redeemed at any time at our option —in whole or in part—at the principal amounts of the notes being redeemed plus accrued and unpaid interest and make-whole amounts, which are defined by the terms of the notes. Certain of the redeemable notes do not require the payment of make-whole amounts if redeemed during a specified period of time immediately prior to the maturity of the notes. Such time periods range from one month to six months prior to maturity.

Debt issuances

During the years ended December 31, 2021 and 2020, we issued debt securities in the following offerings:

- In 2021, we issued $5.0 billion of debt consisting of $1.25 billion of the 1.65% 2028 Notes, $1.25 billion of the 2.00% 2032 Notes, $1.15 billion of the 2.80% 2041 Notes and $1.35 billion of the 3.00% 2052 Notes.
- In 2020, we issued $9.0 billion of debt consisting of $500 million of the 1.90% 2025 Notes, $1.75 billion of the 2.20% 2027 Notes, $1.25 billion of the 2.45% 2030 Notes, $1.25 billion of the 2.30% 2031 Notes, $2.0 billion of the 3.15% 2040 Notes and $2.25 billion of the 3.375% 2050 Notes.

We did not issue any debt or debt securities during the year ended December 31, 2019.

Debt repayments/redemptions

We made debt repayments/redemptions during the years ended December 31, 2021, 2020 and 2019, as follows:

- In 2021, we redeemed $4.2 billion of debt, including the €1.25 billion aggregate principal amount ($1.4 billion upon settlement of the related cross-currency swap) of the 1.25% 2022 euro Notes, the $500 million aggregate principal amount of the 2.70% 2022 Notes, the $1.5 billion aggregate principal amount of the 2.65% 2022 Notes and the $750 million aggregate principal amount of the 3.625% 2022 Notes. In connection with the redemption of these notes, we paid a total of $24 million in make-whole amounts plus associated accrued and unpaid interest, all of which was recognized in Interest expense, net, in the Consolidated Statements of Income.
- In 2020, we repaid/redeemed $6.5 billion of debt, including the repayment at maturity of the $300 million aggregate principal amount of the 4.50% 2020 Notes, the $750 million aggregate principal amount of the 2.125% 2020 Notes, the $300 million Floating Rate Notes due 2020 and the $700 million aggregate principal amount of the 2.20% 2020 Notes. In connection with the redemption of the $900 million aggregate principal amount of the 3.45% 2020 Notes, the $1.0 billion aggregate principal balance of the 4.10% 2021 Notes, the $750 million aggregate principal balance of the 1.85% 2021 Notes and the $1.75 billion aggregate principal balance of the 3.875% 2021 Notes, we paid a total of $96 million in make-whole amounts plus associated accrued and unpaid interest, all of which was recognized in Interest expense, net, in the Consolidated Statements of Income.
- In 2019, we repaid $4.5 billion of debt, including the $1.4 billion aggregate principal amount of the 2.20% 2019 Notes, the $1.0 billion aggregate principal amount of the 5.70% 2019 Notes, the €675 million aggregate principal amount ($864 million upon settlement of the related cross-currency swap) of the 2.125% 2019 euro Notes, the $700 million aggregate principal amount of the 1.90% 2019 Notes and the $550 million Floating Rate Notes due 2019.

Interest rate swaps

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted fixed-rate interest coupons for certain of our debt issuances to floating LIBOR-based coupons over the lives of the respective notes. These interest rate swap contracts qualified and are designated as fair value hedges.

During the year ended December 31, 2021, we entered into interest rate swap contracts with an aggregate notional amount of $1.0 billion with respect to the 2.45% 2030 Notes and an aggregate notional amount of $500 million with respect to the 2.30% 2031 Notes. In connection with the redemption of the 3.625% 2022 Notes, discussed above, associated interest rate swap contracts with an aggregate notional amount of $750 million were terminated.

In connection with the redemption of certain of the notes during the year ended December 31, 2020, discussed above, associated interest rate swap contracts with an aggregate notional value of $3.65 billion were terminated. In addition, because of historically low interest rates, during the year ended December 31, 2020, we terminated interest rate swaps with an aggregate notional amount of $5.2 billion that hedged the 3.625% 2024 Notes, the 2.60% 2026 Notes, the 4.663% 2051 Notes and portions of the 3.625% 2022 Notes and the 3.125% 2025 Notes, which resulted in the receipt of $576 million of cash and reduced counterparty credit risk. Immediately following the terminations of these contracts, we entered into new interest rate swap agreements at then-current interest rates on the same $5.2 billion principal amount of notes. See Note 18, Derivative instruments.

The effective interest rates on notes for which we have entered into interest rate swap contracts and the related notional amounts of these contracts were as follows (dollar amounts in millions):

	December 31, 2021		December 31, 2020	
Notes	**Notional amounts**	**Effective interest rates**	**Notional amounts**	**Effective interest rates**
3.625% 2022 Notes	$ —	N/A	$ 750	LIBOR + 2.7%
3.625% 2024 Notes	1,400	LIBOR + 3.2%	1,400	LIBOR + 3.2%
3.125% 2025 Notes	1,000	LIBOR + 1.8%	1,000	LIBOR + 1.8%
2.60% 2026 Notes	1,250	LIBOR + 1.8%	1,250	LIBOR + 1.8%
2.45% 2030 Notes	1,000	LIBOR + 1.0%	—	N/A
2.30% 2031 Notes	500	LIBOR + 0.8%	—	N/A
4.663% 2051 Notes	1,500	LIBOR +4.1%	1,500	LIBOR + 4.1%
Total notional amounts	$ 6,650		$ 5,900	

N/A = not applicable

Debt exchange

In 2020, we completed a private offering to exchange portions of certain outstanding senior notes due 2037 through 2043 (collectively, Old Notes), listed below, for the $940 million principal amount of the newly issued 2.77% 2053 Notes (the Exchange Offer).

The following principal amounts of each series of Old Notes were validly tendered and subsequently canceled in connection with the Exchange Offer (in millions):

	Principal amount exchanged
6.375% 2037 Notes	$ 74
6.90% 2038 Notes	$ 37
6.40% 2039 Notes	$ 133
5.75% 2040 Notes	$ 39
5.15% 2041 Notes	$ 245
5.65% 2042 Notes	$ 72
5.375% 2043 Notes	$ 76

The 2.77% 2053 Notes bear interest at a lower fixed coupon rate while requiring higher principal repayment at a later maturity date as compared to those of the Old Notes that were exchanged. There were no other significant changes to the terms between the Old Notes and the 2.77% 2053 Notes. In connection with the Exchange Offer, $85 million was paid to holders of the Old Notes (the cash consideration).

The Exchange Offer was accounted for as a debt modification, and accordingly, deferred financing costs and discounts associated with the Old Notes, the cash consideration and the $264 million discount associated with the 2.77% 2053 Notes are being accreted over the term of these newly issued notes and recorded as Interest expense, net, in the Consolidated Statements of Income.

Cross-currency swaps

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. The terms of these contracts effectively convert the interest payments and principal repayments on our 0.41% 2023 Swiss franc Bonds, 2.00% 2026 euro Notes, 5.50% 2026 pound sterling Notes and 4.00% 2029 pound sterling Notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts have been designated as cash flow hedges. For information regarding the terms of these contracts, see Note 18, Derivative instruments.

In connection with the redemption of the 1.25% 2022 euro Notes, discussed above, associated cross-currency swap contracts with an aggregate notional amount of €1.25 billion were terminated.

Shelf registration statement and other facilities

As of December 31, 2021, we have a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. As of December 31, 2021 and 2020, we had no amounts outstanding under our commercial paper program.

In 2019, we amended and restated our $2.5 billion syndicated, unsecured, revolving credit agreement, which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $750 million with the agreement of the banks. Each bank that is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest for any amounts borrowed under this facility, based on our current credit rating, at (i) LIBOR plus 1% or (ii) the highest of (A) the syndication agent bank base commercial lending rate, (B) the overnight federal funds rate plus 0.50% or (C) one-month LIBOR plus 1%. The agreement contains provisions relating to the determination of successor rates to address the possible phase-out or unavailability of designated reference rates. As of December 31, 2021 and 2020, no amounts were outstanding under this facility.

In February 2020, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depository shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depository shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2023.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which requires us to maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2021.

Contractual maturities of debt obligations

The aggregate contractual maturities of all borrowings due subsequent to December 31, 2021, are as follows (in millions):

Maturity dates	Amounts
2022	$ —
2023	1,517
2024	1,400
2025	1,500
2026	2,746
Thereafter	27,075
Total	$ 34,238

Interest costs

Interest costs are expensed as incurred except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest costs capitalized for the years ended December 31, 2021, 2020 and 2019, were not material. Interest paid, including the ongoing impact of interest rate and cross-currency swap contracts, during the years ended December 31, 2021, 2020 and 2019, were $1.2 billion, $1.2 billion and $1.3 billion, respectively.

16. Stockholders' equity

Stock repurchase program

Activity under our stock repurchase program, on a trade date basis, was as follows (in millions):

	Years ended December 31,					
	2021		2020		2019	
	Shares	Dollars	Shares	Dollars	Shares*	Dollars
First quarter	3.7	$ 865	4.3	$ 933	15.9	$ 3,031
Second quarter	6.5	1,592	2.6	591	13.1	2,349
Third quarter	4.6	1,069	3.0	752	6.2	1,170
Fourth quarter	6.9	1,461	5.3	1,221	5.1	1,090
Total stock repurchases	21.7	$ 4,987	15.2	$ 3,497	40.2	$ 7,640

* Total shares do not add due to rounding.

In March 2021, October 2021 and December 2021, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $3.4 billion, $4.5 billion and $5.0 billion, respectively. As of December 31, 2021, $10.9 billion remained available under our stock repurchase program.

Dividends

Our Board of Directors declared quarterly dividends per share of $1.76, $1.60 and $1.45, which were paid in each of the four quarters of 2021, 2020 and 2019, respectively.

Historically, we have declared dividends in December of each year, which were paid in the first quarter of the following fiscal year and in March, July and October, which were paid in the second, third and fourth quarters, respectively, of the same fiscal year. Additionally, on December 3, 2021, the Board of Directors declared a quarterly cash dividend of $1.94 per share of common stock, which will be paid on March 8, 2022, to all stockholders of record as of the close of business on February 15, 2022.

Accumulated other comprehensive loss

The components of AOCI were as follows (in millions):

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2018	$ (670)	$ 241	$ (338)	$ (2)	$ (769)
Foreign currency translation adjustments	(48)	—	—	—	(48)
Unrealized gains	—	127	424	—	551
Reclassification adjustments to income	—	(211)	(56)	—	(267)
Other losses	—	—	—	(5)	(5)
Income taxes	—	18	(8)	—	10
Balance as of December 31, 2019	(718)	175	22	(7)	(528)
Foreign currency translation adjustments	9	—	—	—	9
Unrealized (losses) gains	—	(61)	6	—	(55)
Reclassification adjustments to income	—	(501)	(33)	—	(534)
Other losses	—	—	—	(7)	(7)
Income taxes	—	124	6	—	130
Balance as of December 31, 2020	(709)	(263)	1	(14)	(985)
Foreign currency translation adjustments	(135)	—	—	—	(135)
Unrealized gains (losses)	—	159	(1)	—	158
Reclassification adjustments to income	—	253	—	—	253
Other gains	—	—	—	1	1
Income taxes	—	(88)	—	—	(88)
Balance as of December 31, 2021	$ (844)	$ 61	$ —	$ (13)	$ (796)

With respect to the table above, income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for cash flow hedges were a $33 million expense and a $55 million expense in 2021, a $14 million benefit and a $110 million benefit in 2020 and a $28 million expense and a $46 million benefit in 2019, respectively. Income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for available-for-sale securities were a $1 million expense and a $7 million benefit in 2020 and a $22 million expense and a $14 million benefit in 2019, respectively.

Reclassifications out of AOCI and into earnings were as follows (in millions):

Components of AOCI	Years ended December 31, 2021	2020	2019	Consolidated Statements of Income locations
Cash flow hedges:				
Foreign currency contract (losses) gains	$ (8)	$ 178	$ 101	Product sales
Cross-currency swap contract (losses) gains	(245)	323	110	Other income, net
	(253)	501	211	Income before income taxes
	55	(110)	(46)	Provision for income taxes
	$ (198)	$ 391	$ 165	Net income
Available-for-sale securities:				
Net realized gains	$ —	$ 33	$ 56	Other income, net
	—	(7)	(14)	Provision for income taxes
	$ —	$ 26	$ 42	Net income

Other

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. As of December 31, 2021 and 2020, no shares of preferred stock were issued or outstanding.

17. Fair value measurement

To estimate the fair value of our financial assets and liabilities, we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing an asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing an asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

Level 1	— Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access
Level 2	— Valuations for which all significant inputs are observable either directly or indirectly—other than Level 1 inputs
Level 3	— Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

The fair values of each major class of the Company's financial assets and liabilities measured at fair value on a recurring basis were as follows (in millions):

Fair value measurement as of December 31, 2021, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	$ 47	$ —	$ —	$ 47
U.S. Treasury bills	1,400	—	—	1,400
Money market mutual funds	5,856	—	—	5,856
Other short-term interest-bearing securities	—	1	—	1
Equity securities	611	—	220	831
Derivatives:				
Foreign currency contracts	—	183	—	183
Cross-currency swap contracts	—	66	—	66
Interest rate swap contracts	—	16	—	16
Total assets	$ 7,914	$ 266	$ 220	$ 8,400
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 39	$ —	$ 39
Cross-currency swap contracts	—	339	—	339
Interest rate swap contracts	—	156	—	156
Contingent consideration obligations	—	—	342	342
Total liabilities	$ —	$ 534	$ 342	$ 876

Fair value measurement as of December 31, 2020, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	$ 130	$ —	$ —	$ 130
U.S. Treasury bills	4,948	—	—	4,948
Money market mutual funds	4,765	—	—	4,765
Other short-term interest-bearing securities	—	2	—	2
Equity securities	477	—	—	477
Derivatives:				
Foreign currency contracts	—	28	—	28
Cross-currency swap contracts	—	255	—	255
Interest rate swap contracts	—	66	—	66
Total assets	$ 10,320	$ 351	$ —	$ 10,671
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 237	$ —	$ 237
Cross-currency swap contracts	—	318	—	318
Interest rate swap contracts	—	15	—	15
Contingent consideration obligations	—	—	33	33
Total liabilities	$ —	$ 570	$ 33	$ 603

Interest-bearing and equity securities

The fair values of our U.S. Treasury securities, money market mutual funds and equity investments in publicly traded securities are based on quoted market prices in active markets, with no valuation adjustment. The fair values of equity securities without readily determinable fair values are initially valued at the transaction price and subsequently valued based on a combination of market performance and publicly available information for similar companies that have actively traded equity securities.

Derivatives

All of our foreign currency forward and option derivative contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. These inputs, when applicable, are at commonly quoted intervals. See Note 18, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. See Note 18, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by using an income-based industry-standard

valuation model for which all significant inputs are observable either directly or indirectly. These inputs include LIBOR, swap rates and obligor credit default swap rates. See Note 18, Derivative instruments.

Contingent consideration obligations

As a result of our business acquisitions, we have incurred contingent consideration obligations as discussed below. The contingent consideration obligations are recorded at their fair values by using probability-adjusted discounted cash flows, and we revalue these obligations each reporting period until the related contingencies have been resolved. The fair value measurements of these obligations are based on significant unobservable inputs related to licensing rights and product candidates acquired in business combinations, and they are reviewed quarterly by management in our R&D and commercial sales organizations. The inputs include, as applicable, estimated probabilities and the timing of achieving specified development, regulatory and commercial milestones as well as estimated annual sales. Significant changes that increase or decrease the probabilities of achieving the related development, regulatory and commercial events or that shorten or lengthen the time required to achieve such events or that increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of the obligations, as applicable. Changes in the fair values of contingent consideration obligations are recognized in Other operating expenses in the Consolidated Statements of Income.

Changes in the carrying amounts of contingent consideration obligations were as follows (in millions):

	Years ended December 31,		
	2021	2020	2019
Beginning balance	$ 33	$ 61	$ 72
Additions	309	—	—
Payments	(7)	(6)	—
Net changes in valuations	7	(22)	(11)
Ending balance	$ 342	$ 33	$ 61

As a result of our acquisition of Teneobio in 2021, we are obligated to pay its former shareholders up to $1.6 billion upon achieving separate development and regulatory milestones with regard to various R&D programs. See Note 2, Acquisitions.

As a result of our acquisition of K-A in 2018, we are obligated to make single-digit royalty payments to Kirin contingent upon sales of brodalumab.

As a result of our acquisition of BioVex Group Inc. in 2011, we were obligated to pay its former shareholders upon achieving separate sales-related milestones with regard to IMLYGIC if certain sales thresholds were met. During the year ended December 31, 2020, we determined that the likelihood of achieving these milestones was no longer probable, and accordingly, the obligations were written off.

Summary of the fair values of other financial instruments

Cash equivalents

The fair values of cash equivalents approximate their carrying values due to the short-term nature of such financial instruments.

Borrowings

We estimated the fair values of our borrowings by using Level 2 inputs. As of December 31, 2021 and 2020, the aggregate fair values of our borrowings were $37.9 billion and $39.4 billion, respectively, and the carrying values were $33.3 billion and $33.0 billion, respectively.

Investment in BeiGene

We estimated the fair value of our investment in BeiGene by using Level 1 inputs. As of December 31, 2021 and 2020, the fair values were $5.1 billion and $4.9 billion, and the carrying values were $2.8 billion and $2.9 billion, respectively.

During the years ended December 31, 2021 and 2020, there were no transfers of assets or liabilities between fair value measurement levels, and there were no material remeasurements to the fair values of assets and liabilities that are not measured at fair value on a recurring basis.

18. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we use or have used certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We do not use derivatives for speculative trading purposes.

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates primarily associated with our euro-denominated international product sales. Increases and decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are partially offset by corresponding increases and decreases in the cash flows from our international operating expenses resulting from these foreign currency exchange rate movements. To further reduce our exposure to foreign currency exchange rate fluctuations with regard to our international product sales, we enter into foreign currency forward contracts to hedge a portion of our projected international product sales up to a maximum of three years into the future; and at any given point in time, a higher percentage of nearer-term projected product sales is being hedged than in successive periods.

As of December 31, 2021, 2020 and 2019, we had outstanding foreign currency forward contracts with aggregate notional amounts of $5.7 billion, $5.1 billion and $5.0 billion, respectively. We have designated these foreign currency forward contracts, which are primarily euro based, as cash flow hedges. Accordingly, we report unrealized gains and losses on these contracts in AOCI in the Consolidated Balance Sheets, and we reclassify them to Product sales in the Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term debt denominated in foreign currencies, we enter into cross-currency swap contracts. Under the terms of such contracts, we paid euros, pounds sterling and Swiss francs and received U.S. dollars for the notional amounts at inception of the contracts; and based on these notional amounts, we exchange interest payments at fixed rates over the lives of the contracts by paying U.S. dollars and receiving euros, pounds sterling and Swiss francs. In addition, we will pay U.S. dollars to and receive euros, pounds sterling and Swiss francs from the counterparties at the maturities of the contracts for these same notional amounts. The terms of these contracts correspond to the related hedged debt, thereby effectively converting the interest payments and principal repayment on the debt from euros, pounds sterling and Swiss francs to U.S. dollars. We have designated these cross-currency swap contracts as cash flow hedges. Accordingly, the unrealized gains and losses on these contracts are reported in AOCI in the Consolidated Balance Sheets and reclassified to Other income, net, in the Consolidated Statements of Income in the same periods during which the hedged debt affects earnings.

The notional amounts and interest rates of our cross-currency swaps as of December 31, 2021, were as follows (notional amounts in millions):

	Foreign currency			U.S. dollars	
Hedged notes	**Notional amounts**		**Interest rates**	**Notional amounts**	**Interest rates**
0.41% 2023 Swiss franc Bonds	CHF	700	0.4 %	$ 704	3.4 %
2.00% 2026 euro Notes	€	750	2.0 %	$ 833	3.9 %
5.50% 2026 pound sterling Notes	£	475	5.5 %	$ 747	6.0 %
4.00% 2029 pound sterling Notes	£	700	4.0 %	$ 1,111	4.5 %

During the year ended December 31, 2021, our 1.25% euro Notes were redeemed, and the related cross-currency swaps were settled, resulting in an immaterial loss. During the year ended December 31, 2019, our 2.125% 2019 euro Notes matured, and the related cross-currency swaps were settled.

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts to hedge variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate

contracts, which are designated as cash flow hedges, are recognized in AOCI in the Consolidated Balance Sheets and are amortized into Interest expense, net, in the Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the year ended December 31, 2021, and amounts expected to be recognized during the subsequent 12 months are not material.

The unrealized gains and losses recognized in AOCI for our derivative instruments designated as cash flow hedges were as follows (in millions):

Derivatives in cash flow hedging relationships	Years ended December 31, 2021	2020	2019
Foreign currency contracts	$ 373	$ (251)	$ 148
Cross-currency swap contracts	(214)	190	(21)
Total unrealized gains (losses)	$ 159	$ (61)	$ 127

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified for and were designated as fair value hedges. These interest rate swap contracts effectively convert fixed-rate coupons to floating-rate LIBOR-based coupons over the terms of the related hedge contracts. As of December 31, 2021 and 2020, we had interest rate swap contracts with aggregate notional amounts of $6.7 billion and $5.9 billion, respectively, that hedge certain portions of our long-term debt issuances. See Note 15, Financing arrangements, for information on our interest rate swaps.

During the year ended December 31, 2021, we entered into interest rate swap contracts with an aggregate notional amount of $1.5 billion. Interest rate swaps with an aggregate notional value of $750 million were terminated in connection with the redemption of certain of our notes. The resulting gain on these terminations was immaterial.

During the year ended December 31, 2020, interest rate swaps with an aggregate notional value of $3.7 billion were terminated in connection with the redemption of certain of our notes. The terminations of these interest rate swaps resulted in a gain of $40 million, recognized in Interest expense, net, in the Consolidated Statements of Income. Additionally, we terminated $5.2 billion aggregate notional amount of interest rate swaps, which resulted in receipt of $576 million from the counterparties and which was included in Net cash provided by operating activities in the Consolidated Statements of Cash Flows for the year ended December 31, 2020. This amount is being recognized as a reduction in Interest expense, net, in the Consolidated Statements of Income over the remaining life of the underlying notes. Immediately following the terminations of these interest rate swap contracts, we entered into new interest rate swap agreements at then-current interest rates on the same $5.2 billion principal amount of notes.

For interest rate swap contracts that qualify for and are designated as fair value hedges, we recognize in Interest expense, net, in the Consolidated Statements of Income the unrealized gain or loss on the derivative resulting from the change in fair value during the period, as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. If a hedging relationship involving an interest rate swap contract is terminated, the gain or loss realized on contract termination is recorded as an adjustment to the carrying value of the debt and amortized into Interest expense, net, over the remaining life of the previously hedged debt.

The hedged liabilities and related cumulative-basis adjustments for fair value hedges of those liabilities were recorded in the Consolidated Balance Sheets as follows (in millions):

	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
	December 31,		December 31,	
Consolidated Balance Sheets locations	2021	2020	2021	2020
Current portion of long-term debt	$ 85	$ 89	$ 85	$ 89
Long-term debt	$ 6,729	$ 6,258	$ 199	$ 477

(1) Current portion of long-term debt includes $85 million and $89 million of carrying value with discontinued hedging relationships as of December 31, 2021 and 2020, respectively. Long-term debt includes $440 million and $525 million of carrying value with discontinued hedging relationships as of December 31, 2021 and 2020, respectively.

(2) Current portion of long-term debt includes $85 million and $89 million of hedging adjustments on discontinued hedging relationships as of December 31, 2021 and 2020, respectively. Long-term debt includes $340 million and $425 million of hedging adjustments on discontinued hedging relationships as of December 31, 2021 and 2020, respectively.

Impact of hedging transactions

The following tables summarize the amounts recorded in income and expense line items and the effects thereon from fair value and cash flow hedging, including discontinued hedging relationships (in millions):

	Year ended December 31, 2021		
	Product sales	Other income, net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 24,297	$ 259	$ (1,197)
The effects of cash flow and fair value hedging:			
Losses on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ (8)	$ —	$ —
Cross-currency swap contracts	$ —	$ (245)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ 281
Derivatives designated as hedging instruments	$ —	$ —	$ (192)

	Year ended December 31, 2020		
	Product sales	Other income, net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 24,240	$ 256	$ (1,262)
The effects of cash flow and fair value hedging:			
Gains on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ 178	$ —	$ —
Cross-currency swap contracts	$ —	$ 323	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ 315
Derivatives designated as hedging instruments	$ —	$ —	$ (204)

	Year ended December 31, 2019		
	Product sales	Other income, net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 22,204	$ 753	$ (1,289)
The effects of cash flow and fair value hedging:			
Gains on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ 101	$ —	$ —
Cross-currency swap contracts	$ —	$ 110	$ —
(Losses) gains on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ (349)
Derivatives designated as hedging instruments	$ —	$ —	$ 352

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[1] Gains on hedged items do not completely offset losses on the related designated hedging instruments due to amortization of the cumulative amounts of fair value hedging adjustments included in the carrying amount of the hedged debt for discontinued hedging relationships and the recognition of gains on terminated hedges when the corresponding hedged item was paid down in the period.

No portions of our cash flow hedge contracts were excluded from the assessment of hedge effectiveness. As of December 31, 2021, we expected to reclassify $19 million of net gains on our foreign currency and cross-currency swap contracts out of AOCI and into earnings during the next 12 months.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations in certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. Most of these exposures are hedged on a month-to-month basis. As of December 31, 2021, 2020 and 2019, the total notional amounts of these foreign currency forward contracts were $680 million, $1.0 billion and $1.2 billion, respectively. Gains and losses recognized in earnings for our derivative instruments not designated as hedging instruments were not material for the years ended December 31, 2021, 2020 and 2019.

The fair values of derivatives included in the Consolidated Balance Sheets were as follows (in millions):

	Derivative assets		Derivative liabilities	
December 31, 2021	**Consolidated Balance Sheets locations**	**Fair values**	**Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other noncurrent assets	$ 183	Accrued liabilities/ Other noncurrent liabilities	$ 39
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	66	Accrued liabilities/ Other noncurrent liabilities	339
Interest rate swap contracts	Other current assets/ Other noncurrent assets	16	Accrued liabilities/ Other noncurrent liabilities	156
Total derivatives designated as hedging instruments		265		534
Total derivatives		$ 265		$ 534

	Derivative assets		Derivative liabilities	
December 31, 2020	**Consolidated Balance Sheets locations**	**Fair values**	**Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other noncurrent assets	$ 28	Accrued liabilities/ Other noncurrent liabilities	$ 237
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	255	Accrued liabilities/ Other noncurrent liabilities	318
Interest rate swap contracts	Other current assets/ Other noncurrent assets	66	Accrued liabilities/ Other noncurrent liabilities	15
Total derivatives designated as hedging instruments		349		570
Total derivatives		$ 349		$ 570

Our derivative contracts that were in liability positions as of December 31, 2021, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our, or the surviving entity's, creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right but not the obligation to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the

contracts may be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

The cash flow effects of our derivative contracts in the Consolidated Statements of Cash Flows are included in Net cash provided by operating activities, except for the settlement of notional amounts of cross-currency swaps, which are included in Net cash used in financing activities.

19. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See Part I, Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations.* We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote.

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Our legal proceedings involve various aspects of our business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing, in which we could incur a liability, our opponents seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process, which in complex proceedings of the sort we face often extend for several years. As a result, none of the matters described in this filing, in which we could incur a liability, have progressed sufficiently through discovery and/or the development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain recent developments concerning our legal proceedings and other matters are discussed below:

ANDA Patent Litigation

Otezla ANDA Patent Litigation

Amgen Inc. v. Sandoz Inc., et al.

Beginning in June 2018, Celgene filed 19 separate lawsuits in the U.S. District Court for the District of New Jersey (the New Jersey District Court) against Alkem Laboratories Ltd. (Alkem); Amneal Pharmaceuticals LLC (Amneal); Annora Pharma Private Ltd. and Hetero USA Inc. (collectively, Hetero); Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. (collectively, Aurobindo); Cipla Limited (Cipla Ltd); DRL; Emcure Pharmaceuticals Ltd. and Heritage Pharmaceuticals Inc. (collectively, Emcure); Glenmark Pharmaceuticals Ltd. (Glenmark); Macleods Pharmaceuticals Ltd. (Macleods); Mankind Pharma Ltd. (Mankind); MSN Laboratories Private Limited (MSN); Pharmascience Inc. (Pharmascience); Prinston Pharmaceutical Inc. (Prinston); Sandoz Inc. (Sandoz); Shilpa Medicare Ltd. (Shilpa); Teva Pharmaceuticals USA, Inc. and Actavis LLC (collectively, Actavis); Torrent Pharmaceuticals Ltd. (Torrent); Unichem Laboratories, Ltd. (Unichem); and Zydus Pharmaceuticals (USA) Inc. (Zydus), each for infringement of one or more of the following patents: U.S. Patent Nos. 6,962,940 (the ’940 Patent), 7,208,516 (the ’516 Patent), 7,427,638 (the ’638 Patent), 7,659,302 (the ’302 Patent), 7,893,101 (the ’101 Patent), 8,455,536 (the ’536 Patent), 8,802,717 (the ’717 Patent), 9,018,243 (the ’243 Patent) and 9,872,854 (the ’854 Patent), which are listed in the Orange Book for Otezla. Each of these lawsuits was based on each defendant’s submission of an ANDA seeking FDA approval to market a generic version of Otezla. The New Jersey District Court consolidated these 19 lawsuits for discovery and case management purposes into a single case, *Celgene Corp. v. Sandoz Inc., et al.* Each lawsuit seeks an order of the New Jersey District Court making any FDA approval of the respective defendant’s ANDA effective no earlier than the expiration of the applicable patents.

In August 2018, Celgene filed amended complaints against Alkem, Amneal, Aurobindo, Cipla Ltd, DRL, Glenmark, Pharmascience, Sandoz, Actavis, Unichem and Zydus additionally asserting U.S. Patent No. 9,724,330 (the ’330 Patent), which is listed in the Orange Book for Otezla. Between October 15 and November 27, 2018, Celgene filed amended complaints against Alkem, Amneal, Hetero, Aurobindo, Cipla Ltd, DRL, Emcure, Glenmark, Macleods, Mankind, MSN, Pharmascience, Prinston, Sandoz, Actavis, Torrent, Unichem and Zydus additionally asserting U.S. Patent No. 10,092,541 (the ’541 Patent), which is listed in the Orange Book for Otezla. Between March 1 and April 4, 2019, Celgene filed amended complaints against Hetero, MSN and Emcure for infringement of one or more of the above-listed patents. On October 1, 2019, Celgene filed an amended complaint against Mankind

for infringement of the ’940, ’302, ’536, ’243 and ’330 Patents. On October 8, 2019, Celgene filed a separate lawsuit against Zydus in the New Jersey District Court for infringement of U.S. Patent Nos. 8,093,283 (the ’283 Patent) and 8,629,173, which are not listed in the Orange Book for Otezla. On December 19, 2019, the New Jersey District Court consolidated this lawsuit for discovery and case management purposes into the existing consolidated case, *Celgene Corp. v. Sandoz Inc., et al*. Each defendant has filed an answer to the above-listed complaints and amended complaints disputing infringement and/or validity of the patents asserted against it. Along with their answers, each of Alkem, Hetero, Cipla

Ltd, DRL, Emcure, Glenmark, Macleods, Mankind, Pharmascience, Sandoz, Shilpa, Actavis, Torrent, Unichem and Zydus filed declaratory judgment counterclaims asserting that some or all of the patents are not infringed and/or are invalid. In August 2019, based on a joint request by Celgene and Glenmark, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, having made, using, selling, offering to sell, importing, or distributing of Glenmark's apremilast product during the term of the '940, '638, '302, '101, '536, '243, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement.

Following Amgen's acquisition of the patents-in-suit and the new drug application for Otezla, on February 14, 2020, the New Jersey District Court issued an order substituting Amgen for Celgene as plaintiff in the consolidated action and all related actions, terminating Celgene as plaintiff in the consolidated action and all related actions, and amending the case caption in the consolidated action and all related actions to reflect Amgen as the sole plaintiff.

On March 25, 2020, based on a joint request by Amgen and Unichem, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Unichem's apremilast product during the term of the '940, '638, '302, '101, '536, '243, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On April 3, 2020, based on a joint request by Amgen and Hetero, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Hetero's apremilast product during the term of the '940, '516, '638, '302, '101, '536, '717, '243, '330, '854 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On May 28, 2020, based on a joint request by Amgen and Emcure, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Emcure's apremilast product during the term of the '638, '101, '854 and '541 Patents unless authorized pursuant to a confidential settlement agreement. On July 7, 2020, the New Jersey District Court ordered a stipulated dismissal without prejudice of all claims, counterclaims, and affirmative defenses between Amgen and Sandoz with respect to the '717, '516 and '854 Patents, leaving the '940, '302, '536, '243, '330, '638, '101 and '541 Patents asserted by Amgen against Sandoz in the litigation. On August 6, 2020, based on a joint request by Amgen and Mankind, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Mankind's apremilast product during the term of the '940, '302, '536, '243, '330, '638, '101 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On August 14, 2020, based on a joint request by Amgen and Macleods, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Macleods' apremilast product during the term of the '638 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On October 7, 2020, based on a joint request by Amgen and Amneal, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Amneal's apremilast product during the term of the '101, '940, '638, '302, '536, '243, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On December 30, 2020, based on a joint request by Amgen and Shilpa, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Shilpa's apremilast product during the term of the '638, '101 and '854 Patents, unless authorized pursuant to a confidential settlement agreement. On January 26, 2021, based on a joint request by Amgen and Actavis, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Actavis' apremilast product during the term of the '940, '516, '638, '302, '536, '717, '330, '854 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On March 24, 2021, based on a joint request by Amgen and Prinston, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Prinston's apremilast product during the term of the '638 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On April 6, 2021, based on a joint request by Amgen and Aurobindo, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Aurobindo's apremilast product during the term of the '940, '516, '638, '302, '101, '536, '717, '243, '330, '854 and '541 Patents, unless authorized pursuant to a confidential settlement agreement.

On May 5, 2021, based on a joint request by Amgen and Cipla, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Cipla's apremilast product during the term of the '940, '638, '302, '536, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On May 14, 2021, based on a joint request by Amgen and Torrent, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Torrent's apremilast product during the term of the '101, '638, '854 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On May 19, 2021, based on a joint request by Amgen and Alkem, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling,

offering to sell, or importing of Alkem's apremilast product during the term of the '940, '638, '302, '536, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On May 25, 2021, based on a joint request by Amgen and MSN, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of MSN's apremilast product during the term of the '940, '638, '302, '536, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On June 11, 2021, based on a joint request by Amgen and Pharmascience, the New Jersey District Court entered a consent judgment and

injunction prohibiting the making, using, selling, offering to sell, or importing of Pharmascience's apremilast product during the term of the '243, '940, '638, '302, '101, '536, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On June 17, 2021, based on a joint request by Amgen and DRL, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of DRL's apremilast product during the term of the '638, '101, '536 and '541 Patents, unless authorized pursuant to a confidential settlement agreement.

Trial on the consolidated patent infringement action against Sandoz and Zydus was held at the New Jersey District Court from June 14 to 25, 2021, with closing arguments on July 28, 2021.

On September 28, 2021, consistent with its September 20, 2021 opinion and order, the New Jersey District Court entered final judgment in favor of Amgen and against Zydus with respect to claims 3 and 6 of the '638 Patent, claim 6 of the '536 Patent and claims 2 and 27 of the '283 Patent; and final judgment in favor of Zydus and against Amgen with respect to claims 1 and 15 of the '101 Patent and claims 2, 19 and 21 of the '541 Patent. The final judgment ordered that the effective date of any final approval by the FDA of Zydus's ANDA must be after expiration of the three infringed patents (the '638, '536 and '283 Patents) and any regulatory exclusivity to which Amgen may become entitled. The final judgment also includes an injunction prohibiting Zydus from making, using, offering to sell, or selling in the United States, or importing into the United States, Zydus's generic apremilast products during the term of the three infringed patents. On October 27, 2021, Zydus filed a notice of appeal to the Federal Circuit Court with respect to the '638 Patent. On October 28, 2021, Amgen filed a notice of appeal to the Federal Circuit Court.

On October 12, 2021, the New Jersey District Court also entered final judgment in favor of Amgen and against Sandoz with respect to claims 3 and 6 of the '638 Patent, claim 6 of the '536 Patent and claims 1 and 15 of the '101 Patent; and final judgment in favor of Sandoz and against Amgen with respect to claims 2, 19 and 21 of the '541 Patent. The final judgment ordered that the effective date of any final approval by the FDA of Sandoz's ANDA must be after expiration of the three infringed patents (the '638, '536 and '101 Patents) and any regulatory exclusivity to which Amgen may become entitled. The final judgment also includes an injunction prohibiting Sandoz from making, using, offering to sell, or selling in the United States, or importing into the United States, Sandoz's generic apremilast products during the term of the three infringed patents. On November 9, 2021, Sandoz filed a notice of appeal to the Federal Circuit Court with respect to the '638 and '101 Patents. On November 10, 2021, Amgen filed a notice of appeal to the Federal Circuit Court.

ENBREL Patent Litigation

Immunex Corporation, et al. v. Samsung Bioepis Co., Ltd.

On April 30, 2019, two affiliates of Amgen Inc., Immunex Corporation and Amgen Manufacturing, Limited (collectively, Amgen), along with Hoffmann-La Roche Inc. (Roche), filed a lawsuit in the New Jersey District Court against Samsung Bioepis Co., Ltd. (Bioepis). This lawsuit stems from Bioepis' submission of an application for FDA licensure of an etanercept product as biosimilar to Amgen's ENBREL. Amgen and Roche have asserted infringement of five patents: U.S. Patent Nos. 8,063,182, 8,163,522 (the '522 Patent), 7,915,225, 8,119,605 and 8,722,631. By their complaint, Amgen and Roche seek an injunction to prohibit Bioepis from commercializing its biosimilar etanercept product in the United States prior to the expiry of such patents. On August 5, 2019, Bioepis responded to the complaint, denying infringement and seeking judgment that the patents-in-suit are invalid, unenforceable and/or not infringed. On January 9, 2020 and subject to the terms of a confidential stipulation and court order of January 6, 2020, the New Jersey District Court entered a consent injunction that prohibits Bioepis from making, using, offering to sell, selling or importing into the United States Bioepis' etanercept product. Amgen and Bioepis entered into an agreement with respect to an injunction regarding etanercept as set out in the New Jersey District Court's order of January 6, 2020. On January 15, 2020, the New Jersey District Court entered an order administratively staying the case pursuant to a joint request of Amgen and Bioepis.

On November 2, 2021, Amgen and Bioepis, with the consent of Roche, jointly submitted to the New Jersey District Court a confidential stipulation and a form of final judgment and order of permanent injunction resolving the dispute between the parties and enjoining Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, any product containing etanercept until the April 24, 2029 expiry of Roche's '522 Patent. On November 3, 2021, the New Jersey District Court entered final judgment and ordered a permanent injunction against Bioepis in conformity with the parties' submission.

Repatha Patent Litigation

Amgen Inc., et al. v. Sanofi, et al.

In October 2014, Amgen initiated a series of lawsuits that were consolidated by the U.S. District Court for the District of Delaware (Delaware District Court) in December 2014 into a single case against Sanofi, Sanofi-Aventis U.S. LLC and Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc. (collectively, Sanofi) and Regeneron Pharmaceuticals, Inc. (Regeneron), addressing seven of our patents: U.S. Patent Nos. 8,563,698; 8,829,165 (the '165 Patent); 8,859,741 (the '741 Patent); 8,871,913; 8,871,914; 8,883,983; and 8,889,834. These patents describe and claim monoclonal antibodies to PCSK9. By its complaints, Amgen seeks an injunction to prevent the infringing manufacture, use and sale of Sanofi and Regeneron's alirocumab, a monoclonal antibody targeting PCSK9. In January 2016, the Delaware District Court granted Amgen's motion to amend the complaint to add its affiliates, Amgen Manufacturing, Limited and Amgen USA Inc., as plaintiffs and to add the allegation that Sanofi and Regeneron's infringement of Amgen's patents is willful.

In February 2016, the Delaware District Court entered a stipulated order finding alirocumab and the drug product containing it, PRALUENT infringe certain of Amgen's patents, including claims 2, 7, 9, 15, 19 and 29 of the '165 Patent and claim 7 of the '741 Patent. In March 2016, the Delaware District Court entered judgment in favor of Amgen following a five-day jury trial and a unanimous jury verdict that these patent claims are all valid. In January 2017, the Delaware District Court denied Sanofi and Regeneron's post-trial motions seeking a new trial and for judgment as a matter of law, and granted Amgen's motion for a permanent injunction prohibiting the infringing manufacture, use, sale, offer for sale or import of alirocumab in the United States. Sanofi and Regeneron filed an appeal of the judgment and the permanent injunction to the Federal Circuit Court. In February 2017, following a motion by Sanofi and Regeneron, the Federal Circuit Court entered a stay of the permanent injunction during the pendency of the appeal. In October 2017, the Federal Circuit Court reversed in part the judgment of the Delaware District Court and remanded for a new trial two of the patent validity defenses (lack of written description and enablement of the claimed inventions), and affirmed the Delaware District Court's judgment of infringement of claims 2, 7, 9, 15, 19 and 29 of the '165 Patent and claim 7 of the '741 Patent and the third patent validity defense (finding that the claimed inventions were not obvious to a person of ordinary skill in the field of the patents).

In March 2018, the Federal Circuit Court issued a mandate returning the case to the Delaware District Court for a new trial on two of Sanofi and Regeneron's challenges to the validity of our patents (lack of written description and enablement of the claimed inventions) and for further consideration of a permanent injunction. In July 2018, Amgen filed a petition for certiorari with the U.S. Supreme Court seeking review of the Federal Circuit Court's conclusion that the judgment affirming the validity of Amgen's patents was based, in part, on an erroneous application of the law of written description. On January 7, 2019, the U.S. Supreme Court denied Amgen's petition for certiorari. On remand, the Delaware District Court scheduled a new trial on Sanofi and Regeneron's challenges to the validity of our patents based on lack of written description and enablement of the claimed inventions. The Delaware District Court also entered judgment on the pleadings for Sanofi and Regeneron on Amgen's claim of willful infringement.

On February 25, 2019, a jury of the Delaware District Court again unanimously upheld the validity of claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent. The jury also found that claims 7 and 15 of the '165 Patent meet the enablement requirement, but are invalid for failure to meet the written description requirement. On March 18, 2019, Sanofi and Regeneron filed post-trial motions seeking to reverse the jury verdict against them or for a new trial, and Amgen filed a motion for a permanent injunction. On August 28, 2019, the Delaware District Court ruled on the post-trial motions, denying Sanofi and Regeneron's request for a new trial and their request to reverse the jury verdict that the '165 Patent and the '741 Patent provide written description support for the claimed inventions. The Delaware District Court also ruled as a matter of law that claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent are invalid for failing to meet the enablement requirement, overturning the jury verdict.

On October 23, 2019, Amgen filed a notice of appeal to the Federal Circuit Court and based on the subsequent hearing, on February 11, 2021 the Federal Circuit Court issued a decision affirming the Delaware District Court's ruling. Amgen filed a petition for rehearing en banc which was denied on June 21, 2021. On November 18, 2021, Amgen filed a petition for writ of certiorari with the U.S. Supreme Court seeking review of the invalidation of claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent as lacking an enabling disclosure of the invention. On January 11, 2022, the U.S. Supreme Court requested that Sanofi and Regeneron file a response to Amgen's petition, which is due March 14, 2022.

Patent Disputes in the International Region

We are involved in and expect future involvement in additional disputes regarding our PCSK9 patents in other jurisdictions and regions. This includes matters filed against us and that we have filed in Germany, Spain and Japan.

In February 2016, the European Patent Office (EPO) granted European Patent No. 2,215,124 (EP 2,215,124) to Amgen. This patent describes and claims monoclonal antibodies to PCSK9 and methods of treatment and Sanofi filed an opposition to the patent in the EPO seeking to invalidate it. In November 2016, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A. and Sanofi Winthrop Industrie S.A. filed a joint opposition against Amgen's patent, and each of Lilly, Regeneron and Strawman Ltd. also filed oppositions to Amgen's patent. In November 2018, the EPO confirmed the validity of Amgen's EP 2,215,124, which was appealed to the Technical Board of Appeal (TBA). On October 29, 2020, the TBA upheld the validity of certain claims, including claims that protect Repatha, but ruled that broader claims encompassing PRALUENT were invalid. As a result of the TBA's decision, national litigations regarding PRALUENT in Europe are in the process of being resolved. In Germany, Sanofi-Aventis Deutschland GmbH and Regeneron have filed actions seeking damages arising from the provisional enforcement of an injunction against PRALUENT that was lifted after the TBA's October 29, 2020 ruling.

On April 24, 2020, the Supreme Court of Japan declined to hear Sanofi K.K.'s appeals making final the Japanese High Court's decisions that PRALUENT infringes Amgen's valid patent rights in Japan. On June 24, 2020, Amgen filed written answers to the invalidity trials initiated by Regeneron on February 12, 2020 before the Japan Patent Office seeking to invalidate Amgen's Japanese patents that were previously held infringed by PRALUENT and valid over challenges filed by Sanofi K.K. The Japanese Patent Office dismissed Regeneron's invalidity trials and Regeneron has appealed the decisions to the Japanese High Court. Damages proceedings against Sanofi K.K. are ongoing before the Tokyo District Court, where Sanofi K.K. has initiated new validity challenges to Amgen patents in Japan.

NEUPOGEN (filgrastim)/Neulasta Patent Litigation

Amgen Inc., et al. v. Hospira Inc. et al.

On February 11, 2020, Amgen Inc. and its wholly owned subsidiary, Amgen Manufacturing, Limited (collectively, Amgen), filed a lawsuit in the Delaware District Court against Hospira Inc. and Pfizer Inc. (collectively, Pfizer). This lawsuit stems from Pfizer's submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen's Neulasta. Amgen has asserted infringement of U.S. Patent No. 8,273,707 (the '707 Patent) and seeks, among other remedies, injunctive relief to prohibit Pfizer from infringing the '707 Patent. On March 4, 2020, Pfizer filed a motion requesting the Delaware District Court to dismiss the complaint by Amgen alleging noninfringement of the '707 Patent. In June 2020, the FDA approved Pfizer's NYVEPRIA, a biosimilar to Amgen's Neulasta.

On April 6, 2021, the Delaware District Court stayed further proceedings in the matter pending claim construction of the patent claims and, based on a subsequent hearing, determined on June 11, 2021 that the term at issue required no construction. Currently pending before the Delaware District Court is Pfizer's motion for summary judgment of noninfringement, which has been fully briefed. No date has been set for argument on the motion.

Patent Trial and Appeal Board (PTAB) Challenge

Apotex PTAB Challenge

In February 2017, the PTAB of the USPTO granted Apotex's petition to institute inter partes review (IPR) proceeding of U.S. Patent No. 8,952,138 (the '138 Patent), challenging claims of the '138 Patent as unpatentable. In May 2017, Amgen filed its response. In February 2018, the PTAB issued a final decision holding all but one claim of the '138 Patent as unpatentable and Apotex filed a request for rehearing in March 2018.

On May 20, 2019, the PTAB issued a decision denying Apotex's request for rehearing on the PTAB's finding and sua sponte amending the final decision with a finding that the one remaining claim in Amgen's '138 Patent is unpatentable. On July 22, 2019, Amgen filed a notice of appeal to the Federal Circuit Court with respect to all claims held to be unpatentable. On August 5, 2019, Apotex provided notice that it would not participate in the appeal. On September 16, 2019, the USPTO filed a notice of intervention on the appeal. On March 24, 2020, the Federal Circuit Court vacated the decision by the PTAB and remanded the case to the PTAB for proceeding consistent with the Federal Circuit Court's decision in *Arthrex Inc. v. Smith & Nephew, Inc*., 941 F.3d 1320 (Fed. Cir. 2019).

On July 14, 2020, Amgen and Apotex filed a joint motion to terminate the IPR proceedings stating that there is no current dispute between the parties with respect to the '138 Patent. On July 29, 2020, the U.S. government filed a petition for writ of certiorari with respect to the cases that the Federal Circuit Court remanded to the PTAB, including the case regarding the '138 Patent, for proceedings consistent with its decision in *Arthrex Inc. v. Smith & Nephew,*

Inc., requesting that such remanded cases be held pending the U.S. Supreme Court's disposition of the petition for writ of certiorari in *United States v. Arthrex, Inc.*, No. 19-1434. On August 25, 2020, Amgen filed its response to the U.S. government's petition for writ of certiorari indicating that Amgen did not intend to respond unless requested by the U.S. Supreme Court.

On June 21, 2021, the U.S. Supreme Court decided *United States v. Arthrex, Inc.* On June 28, 2021, the U.S. Supreme Court granted the government's pending certiorari petition and vacated and remanded the Federal Circuit Court's judgment for further consideration under *Arthrex.*

On September 2, 2021, the Federal Circuit Court issued a remand to permit Amgen to request rehearing of the PTAB's final written decision holding that all claims of the '138 Patent as unpatentable.

On October 4, 2021, Amgen filed a request for the USPTO Director for a rehearing and review of the Final Written Decision pursuant to *Arthrex*. On November 22, 2021, the Director denied this request. On December 6, 2021, Amgen filed the Notice of Director review with the patent office.

Pfizer PTAB Challenge

On February 10, 2021, Pfizer filed a petition to institute IPR proceeding at the USPTO of U.S. Patent No. 8,273,707 (the '707 Patent), challenging claims of the '707 Patent as unpatentable. Amgen's preliminary response was filed on May 18, 2021.

On August 17, 2021, the PTAB of the USPTO granted Pfizer's petition to institute IPR of the '707 Patent. On August 23, 2021, the PTAB issued the schedule for the proceeding, including oral argument (if requested) on May 18, 2022. On November 17, 2021, Amgen filed its Patent Owner's Response.

Breach of Contract Action

Novartis Pharma AG v. Amgen Inc.

On April 4, 2019, Amgen filed a lawsuit in the U.S. District Court for the Southern District of New York (the New York Southern District Court) against Novartis seeking a declaratory judgment that Novartis materially breached two collaboration agreements Amgen and Novartis entered into in 2015 and 2017 (the 2015 Agreement and the 2017 Agreement, respectively) related to the development and commercialization of Aimovig due to Novartis' affiliate Sandoz GmbH entering into a contract manufacturing agreement with Alder BioPharmaceuticals, Inc. (Alder) related to eptinezumab, an expected direct competitor to Aimovig and entrant in the CGRP-related migraine therapy market. Amgen seeks to terminate its collaboration agreements with Novartis and also seeks damages from Novartis for breach of contract and negligent misrepresentation. Also on April 4, 2019, Novartis initiated a separate lawsuit against Amgen in the same court seeking declaratory judgment that Novartis, alternatively, did not materially breach the collaboration agreements or, even if it did breach the collaboration agreements, such breach was not material and has been cured, and that Amgen may not terminate the collaboration agreements. On April 8, 2019, Amgen answered Novartis' complaint and filed counterclaims seeking a declaratory judgment that Novartis materially breached the collaboration agreements due to its affiliate Sandoz GmbH entering into the contract manufacturing agreement with Alder. In its counterclaim, Amgen seeks to terminate its collaboration agreements with Novartis and also seeks damages from Novartis for breach of contract and negligent misrepresentation. On July 16, 2019, Novartis filed an amended complaint adding a claim for breach of contract alleging Novartis is owed amounts associated with 2018 budget overruns, and Amgen responded with a counterclaim alleging additional breaches by Novartis of the collaboration agreements. On September 17, 2019 and October 8, 2019, Novartis and Amgen, respectively, each filed its motion for judgment on the pleadings. On February 3, 2020, Amgen was granted leave to file its amended counterclaims. On February 4, 2020, Amgen filed its amended answer to Novartis' first amended complaint and second amended counterclaims for affirmative relief to add a fraudulent inducement claim. On February 18, 2020, Novartis filed its answer and affirmative defenses to Amgen's second amended counterclaims.

On June 9, 2020, the New York Southern District Court entered an order granting Novartis' motion for judgment on the pleadings that Novartis did not breach the 2017 Agreement, and denying Amgen's motions for judgment on the pleadings seeking dismissal of Novartis' amended complaint that Novartis did not breach the 2015 Agreement or the 2017 Agreement, and Novartis timely cured any breach. On June 23, 2020, Amgen filed a motion for clarification and/or reconsideration of the June 9, 2020 order, which was denied on September 14, 2020.

On June 2, 2021, the parties executed agreements to settle two claims in the litigation, relating to the 2018 budget overrun dispute and certain counterclaims alleging breaches by Novartis of the 2015 and 2017 Agreements related to the development and commercialization of Aimovig, and to amend and restate the 2017 collaboration agreement. As part of the agreement, Amgen paid $48 million to Novartis to resolve the 2018 budget dispute.

On October 26, 2021, the New York Southern District Court held a status conference with the parties and set the dates for Novartis' opening brief for its motion for partial summary judgment on two claims, fraudulent inducement and negligent misrepresentation.

On January 31, 2022, the parties resolved all claims in the litigation.

Antitrust Class Action

Sensipar Antitrust Class Actions

From February to April 2019, four plaintiffs filed putative class action lawsuits against Amgen and various entities affiliated with Teva Pharmaceuticals USA, Inc. (Teva) alleging anticompetitive conduct in connection with settlements between Amgen and manufacturers of generic cinacalcet product. Two of those actions were brought in the Delaware District Court, captioned *UFCW Local 1500 Welfare Fund v. Amgen Inc., et al.* (February 21, 2019) (Local 1500) and *Cesar Castillo, Inc. v. Amgen Inc., et al.* (February 26, 2019) (Castillo). The third action was brought in the New Jersey District Court, captioned *Teamsters Local 237 Welfare Fund, et al. v. Amgen Inc., et al.* (March 14, 2019) (Local 237) and the fourth action was brought in the U.S. District Court for the Eastern District of Pennsylvania (the Eastern Pennsylvania District Court), captioned *KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. v. Amgen Inc., et al* (April 10, 2019) (KPH). Each of the lawsuits is brought on behalf of a putative class of direct or indirect purchasers of Sensipar and alleges that the plaintiffs have overpaid for Sensipar as a result of Amgen's conduct that allegedly improperly delayed market entry by manufacturers of generic cinacalcet products. The lawsuits focus predominantly on the settlement among Amgen, Watson Laboratories, Inc. (Watson) and Teva of the parties' patent infringement litigation. Each of the lawsuits seeks, among other things, treble damages, equitable relief and attorneys' fees and costs. On April 10, 2019, the plaintiff in the KPH lawsuit filed a motion seeking to have the four lawsuits consolidated and designated as a multidistrict litigation (MDL) in the Eastern Pennsylvania District Court, and the plaintiff in the Local 1500 lawsuit filed a motion seeking to have the four lawsuits, along with *Cipla Ltd. v. Amgen Inc.*, consolidated and designated as an MDL in the Delaware District Court.

On July 31, 2019, the MDL panel entered an order consolidating in the Delaware District Court the four class action lawsuits. On September 13, 2019, the plaintiffs filed amended complaints, and on October 15, 2019, Amgen filed its motion to dismiss both the direct purchaser plaintiffs' consolidated class action complaint and the indirect purchaser end payor plaintiffs' complaint. On December 6, 2019, the plaintiffs responded to Amgen's motion to dismiss and, on January 10, 2020, Amgen filed its response. On February 6, 2020, the motions in the class action lawsuits were transferred to the U.S. Magistrate Judge for the District of Delaware (Magistrate Judge) for a recommendation. The MDL panel certified its conditional transfer order on February 6, 2020 transferring the additional class action lawsuit brought in the U.S. District Court for the Southern District of Florida, captioned *MSP Recovery Claims v. Amgen Inc., et al.*, to the Delaware District Court.

On July 22, 2020, the Magistrate Judge issued a recommendation to the Delaware District Court that the claims against Amgen be dismissed but leave be given to plaintiffs to amend their complaints. On August 5, 2020, the plaintiffs filed objections to the Magistrate Judge's report and recommendation. On August 19, 2020, Amgen filed a response to the plaintiffs' objections. On November 30, 2020, the District Court adopted the Magistrate Judge's recommendation in part and denied it in part, denying Amgen's motion to dismiss on the grounds that plaintiffs adequately alleged reverse payment claims but granted Amgen's motion to dismiss with respect to the other Federal antitrust claims. On December 23, 2020, Teva, Watson and Actavis filed a motion for interlocutory appeal and for a stay pending appeal and Amgen filed its joinder (the 1292 Motion). On January 5, 2021, a joint status report was filed advising the Delaware District Court that the defendants are still considering whether to withdraw the 1292 Motion and plaintiffs' offer to stay discovery, pending further rulings on motions to dismiss the amended complaints. On January 19, 2021, a joint status report was filed pursuant to the Delaware District Court's January 6, 2021 order along with a stipulation to defer the 1292 Motion until after rulings on the amended complaints.

On February 16, 2021, the plaintiffs in the antitrust class action lawsuit brought on behalf of putative classes of direct or indirect purchasers of Sensipar filed their amended complaints. On March 4, 2021, a stipulation and order regarding the filing of a second amended complaint were filed to add another plaintiff: Teamsters Western Region & Local 177 Health Care Fund. On March 17, 2021, a defendant, MSP Recovery Claims, Series LLC, filed its notice of voluntary dismissal. On March 30, 2021, the remaining defendants, including Amgen, filed their motions to dismiss the second amended complaint.

On April 27, 2021, plaintiffs filed their oppositions to defendants' (including Amgen's) motion to dismiss, and defendants' reply was filed on May 25, 2021. A hearing on defendants' motion to dismiss was held in the Delaware District Court on July 13, 2021.

Humira Biosimilar Antitrust Class Actions

From March to May 2019, twelve purported class actions against Amgen, along with AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively, AbbVie), were filed in the U.S. District Court for the Northern District of Illinois (the Illinois Northern District Court). The cases are captioned: *UFCW Local 1500 Welfare Fund v. AbbVie Inc., et al.* (March 18, 2019) (Local 1500); *Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund v. AbbVie Inc., et al.* (March 20, 2019); *Mayor and City Council of Baltimore v. AbbVie Inc., et al.* (March 22, 2019); *Pipe Trades Services MN Welfare Fund v. AbbVie Inc., et al.* (March 29, 2019); *St. Paul Electrical Workers' Health Plan v. AbbVie Inc., et al.* (March 29, 2019); *Welfare Plan of the International Union of Operating Engineers Locals 137, 137A, 137B, 137C and 137R v. AbbVie Inc., et al.* (April 1,

2019); *Law Enforcement Health Benefits, Inc. v. AbbVie, Inc., et al.* (April 9, 2019) (Law Enforcement); *Kentucky Laborers District Council Health and Welfare Fund v. AbbVie, Inc., et al.* (April 16, 2019); *Sheet Metal Workers' Local Union No. 28 Welfare Fund v. AbbVie, Inc., et al.* (April 19, 2019) (Sheet Metal Workers'); *Locals 302 & 612 of The International Union of Operating Engineers-Employers Construction Industry Health And Security Trust Fund v. AbbVie Inc., et al.* (April 25, 2019) (Construction Industry); *Louisiana Health Service & Indemnity Co., d/b/a Blue Cross and Blue Shield of Louisiana and HMO Louisiana, Inc. v. AbbVie Inc.*, *et al.* (April 30, 2019) (Louisiana Health); and *Cleveland Bakers and Teamsters Health and Welfare Fund v. AbbVie Inc., et al.* (May 10, 2019) (Cleveland Bakers) (collectively, Humira Antitrust Class Actions).

In each of the Humira Antitrust Class Actions, the plaintiffs bring federal antitrust claims along with various state law claims under common law and antitrust, consumer protection and unfair competition statutes. In each case, the plaintiffs specifically allege that AbbVie has unlawfully monopolized the alleged market for Humira and biosimilars of Humira, including by creating an allegedly unlawful so-called patent thicket around Humira. In the Local 1500, Sheet Metal Workers' and Construction Industry cases, the plaintiffs further allege that AbbVie entered into allegedly unlawful market division agreements with Amgen and other companies that had developed Humira biosimilars, including Bioepis, Mylan, Sandoz, Fresenius Kabi USA, LLC (Fresenius), Pfizer Inc. and Momenta Pharmaceuticals, Inc., in connection with the settlement of patent litigation relating to Humira, whereby Amgen and the other defendants that have developed Humira biosimilars were permitted to market those products in Europe as early as October 2018, while remaining off the market in the United States until 2023. In each of the Humira Antitrust Class Actions other than the Local 1500 and Construction Industry cases, the plaintiffs allege that AbbVie and Amgen entered into an allegedly unlawful settlement agreement under which Amgen allegedly agreed to delay its entry into the U.S. market with AMGEVITA, its Humira biosimilar, in exchange for an alleged promise of exclusivity as the sole Humira biosimilar in that market for five months, beginning in January 2023. In each of the Humira Antitrust Class Actions, plaintiffs seek injunctive relief, treble damages and attorney's fees on behalf of a putative class of third-party payers and/or consumers that have indirectly purchased, paid for or provided reimbursement for Humira in the United States. Defendants' responses to the first six complaints were stayed by the court. On June 4, 2019, the Illinois Northern District Court entered an order consolidating the twelve purported class action cases for pre-trial purposes.

On August 9, 2019, the plaintiffs filed their consolidated complaint, naming as defendants Amgen, along with AbbVie, Bioepis, Sandoz and Fresenius. On October 11, 2019, the defendants filed a joint motion to dismiss the consolidated complaint (as well as brief individual motions), challenging the legal sufficiency of the plaintiffs' allegations to state any claim for relief under the law. On November 19, 2019, plaintiffs filed their opposition to the motion to dismiss. On December 20, 2019, defendants filed their reply in support of the motion to dismiss. On June 8, 2020, the Illinois Northern District Court issued an order granting the motion by the defendants to dismiss the consolidated class action complaint. On June 29, 2020, the plaintiffs filed a status report asking the Illinois Northern District Court to convert the dismissal to one with prejudice. On June 30, 2020, the Illinois Northern District Court granted the motion. On July 28, 2020, the plaintiffs filed a notice of appeal. On October 5, 2020, the plaintiffs-appellants filed their opening brief to the U.S. Court of Appeals for the Seventh Circuit. Plaintiffs-appellants amicus briefs were filed in October 2020, including one by the FTC and one on behalf of 20 states, each filed on October 13, 2020. On December 21, 2020, the defendants-appellees filed their opposition brief. Defendants-appellees amicus briefs, including one by the DoJ, were filed on December 28, 2020. On February 25, 2021, oral argument was held by the U.S. Court of Appeals for the Seventh Circuit on the appeal by plaintiffs-appellants of the lower court's dismissal of the consolidated complaint with prejudice.

U.S. Tax Litigation

Amgen Inc. & Subsidiaries v. Commissioner of Internal Revenue

See Note 6, Income taxes, for discussion of the IRS tax dispute and the Company's petition in the U.S. Tax Court.

Commitments – U.S. repatriation tax

Under the 2017 Tax Act, we elected to pay in eight annual installments the repatriation tax related primarily to prior indefinitely invested earnings of our foreign operations. The following table summarizes the remaining scheduled repatriation tax payments as of December 31, 2021 (in millions):

2022	$
2023	
2024	
2025	
Total remaining U.S. repatriation tax commitments	$

SCHEDULE II

AMGEN INC.

VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2021, 2020 and 2019

(In millions)

Allowance for doubtful accounts	Balance at beginning of period	Additions charged to costs and expenses	Other additions	Deductions	Balance at end of period
Year ended December 31, 2021	$ 32	$ —	$ —	$ (6)	$ 26
Year ended December 31, 2020	$ 26	$ 8	$ —	$ (2)	$ 32
Year ended December 31, 2019	$ 48	$ —	$ —	$ (22)	$ 26

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 O**
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

or

☐ **TRANSITION REPORT PURSUANT TO SECTION**
SECURITIES EXCHANGE ACT OF 1934

Commission file number 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**95-3540776**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive **Thousand Oaks** **California**	**91320-1799**
(Address of principal executive offices)	(Zip Code)

(805) 447-1000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol (s)	Name of each exchange on which registered
Common stock, $0.0001 par value	**AMGN**	**The Nasdaq Stock Market LLC**
1.250% Senior Notes Due 2022	**AMGN22**	**The Nasdaq Stock Market LLC**
2.00% Senior Notes Due 2026	**AMGN26**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller re company
☒	☐	☐	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $138,056,968,288 as of June 30, 2020.[(A)]

(A) Excludes 1,045,777 shares of common stock held by directors and executive officers, and any stockholders whose ownership exceeds ten percent of the shares outstanding, at June 30, 2020. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

577,566,383

(Number of shares of common stock outstanding as of February 3, 2021)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2021 Annual Meeting of Stockholders to be held May 18, 2021, are incorporated by reference into Part III of this annual report.

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PART I

Item 1. BUSINESS

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen was incorporated in California in 1980 and became a Delaware corporation in 1987. We have a presence in approximately 100 countries worldwide. Amgen operates in one business segment: human therapeutics.

Significant Developments

Following is a summary of significant developments affecting our business that have occurred and that we have reported since the filing of our Annual Report on Form 10-K for the year ended December 31, 2019.

COVID-19 pandemic

A novel strain of coronavirus (SARS-CoV-2, or severe acute respiratory syndrome coronavirus 2, causing coronavirus disease 19, or COVID-19) was declared a global pandemic by the World Health Organization (WHO) on March 11, 2020. Since the first quarter of 2020 and continuing into 2021, we have seen some impact of the pandemic to our operations. We continue to monitor and respond as the pandemic evolves to ensure the continued development, manufacture and distribution of our medicines. For further discussion, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview, Selected Financial Information and Results of Operations. For a discussion of the risks presented by the COVID-19 pandemic to our results, see Risk Factors in Item 1A. Also see the remainder of Item 1. Business for discussion of pandemic-related impacts to our overall business.

Products/Pipeline

Oncology/Hematology

KYPROLIS® (carfilzomib)

- In August 2020, we announced that the U.S. Food and Drug Administration (FDA) had approved the expansion of the KYPROLIS® U.S. prescribing information to include its use in combination with DARZALEX® (daratumumab) plus dexamethasone in two dosing regimens—once weekly and twice weekly—for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three previous lines of therapy.

Sotorasib (formerly AMG 510)

- In September 2020, we announced updated phase 1 data evaluating sotorasib in 129 patients across multiple advanced solid tumors with Kirsten rat sarcoma viral oncogene homolog (*KRAS) G12C* mutation, which were published in the New England Journal of Medicine. Data from 59 patients with advanced non-small cell lung cancer (NSCLC) were also featured in an oral presentation at a September 2020 medical conference. In the patients with advanced NSCLC who were treated with the 960 mg daily dose, the confirmed objective response rate (ORR) was 35.3%. Across all dose levels, the confirmed ORR was 32.2%, with median duration of response of 10.9 months and median progression-free survival (PFS) of 6.3 months; 10 of 19 responders were still in response as of the data cutoff.

- In October 2020, we announced top-line phase 2 results in 126 patients with *KRAS G12C*-mutant advanced NSCLC. Sotorasib demonstrated an ORR (primary endpoint) consistent with previously reported phase 1 data in patients taking the 960 mg daily dose. Other measures of efficacy, including duration of response,

were promising, and more than half of the responders were still on treatment and continuing to respond as of the data cutoff date. The results of this phase 2 study are potentially registrational, and a phase 3 confirmatory study comparing sotorasib to docetaxel is currently recruiting patients with *KRAS G12C*-mutant advanced NSCLC.

- In December 2020, we announced that the FDA had granted Breakthrough Therapy designation for our investigational $KRAS^{G12C}$ inhibitor, sotorasib, for the treatment of patients with locally advanced or metastatic NSCLC with *KRAS G12C* mutation, as determined by an FDA-approved test, following at least one prior systemic therapy. Following this announcement, we submitted a New Drug Application (NDA) to the FDA. The sotorasib NDA is being reviewed by the FDA's Real-Time Oncology Review (RTOR) pilot program, which aims to explore a more efficient review process that ensures safe and effective treatments are made available to patients as early as possible. Later in December, we also submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA).

- In January 2021, we announced results from the phase 2 cohort of the clinical study evaluating sotorasib in 126 patients with *KRAS G12C*-mutant advanced NSCLC. Sotorasib demonstrated a confirmed ORR and disease control rate of 37.1% and 80.6%, respectively, a median duration of response of 10 months and median progression-free survival of 6.8 months. In addition, sotorasib was granted Breakthrough Therapy designation by the Center for Drug Evaluation of the National Medical Products Administration in China.

RIABNI™ (rituximab-arrx) (formerly ABP 798)

- In December 2020, we announced that the FDA had approved RIABNI™, a biosimilar to Rituxan® (rituximab), for the treatment of adult patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, granulomatosis with polyangiitis (Wegener's granulomatosis) and microscopic polyangiitis. RIABNI™ launched in the United States in January 2021.

Inflammation

Otezla® (apremilast)

- In May 2020, we announced positive top-line results from a phase 3 study to assess the efficacy of Otezla® in adults with mild-to-moderate plaque psoriasis. The study showed that oral Otezla® 30 mg twice daily achieved a statistically significant improvement, compared with placebo, in the primary endpoint of the static Physician's Global Assessment (sPGA) response (defined as an sPGA score of clear (0) or almost clear (1) with at least a 2-point reduction from baseline) at week 16.

Enbrel® (etanercept)

- In July 2020, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment by the U.S. District Court for the District of New Jersey upholding the validity of the two patents that describe and claim ENBREL and methods for making it. See Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Tezepelumab

- In November 2020, we and AstraZeneca plc (AstraZeneca) announced positive top-line results from the registrational phase 3 NAVIGATOR trial in adults and adolescents with severe uncontrolled asthma. The trial met the primary endpoint with tezepelumab added to standard of care (SoC), demonstrating a statistically significant and clinically meaningful reduction compared with placebo plus SoC in the annualized asthma exacerbation rate (AAER) over 52 weeks in the overall patient population. SoC consisted of medium- or high-dose inhaled corticosteroids (ICS) plus at least one additional controller medication with or without oral corticosteroids (OCS). We expect to submit results of this study to regulators in 2021.

- In December 2020, we and AstraZeneca announced that the SOURCE trial had not met the primary endpoint of a statistically significant reduction in the daily OCS dose, without loss of asthma control, with tezepelumab compared to placebo. The results of this trial have no impact on our submission plans.

Cardiovascular

Omecamtiv mecarbil

- In November 2020, based on results of the omecamtiv mecarbil phase 3 trial, we provided notice to Cytokinetics, Incorporated (Cytokinetics) of termination of our collaboration and our intention to transition to them the development and commercialization rights for omecamtiv mecarbil and AMG 594.

Establishment of wholly owned affiliate in Japan

- In April 2020, we completed our purchase from Astellas of the remaining shares of Amgen Astellas BioPharma K.K. (AABP), a joint venture between Amgen and Astellas established in 2013. AABP, now a wholly owned Amgen affiliate in Japan and renamed Amgen K.K., has enabled us to build a strong presence in Japan as we continue to advance treatments for serious illnesses. The purchase did not have a material impact to our consolidated financial statements.

Marketing, Distribution and Selected Marketed Products

The largest concentration of our sales and marketing forces is based in the United States and Europe. In addition, we continue to expand the commercialization and marketing of our products into other geographic territories, including parts of Asia, the Middle East, Canada and Latin America. This expansion is occurring by establishing our own affiliates, by acquiring existing third-party businesses or product rights or by collaborating with third parties. See Business Relationships for our significant alliances. Whether we use our own sales and marketing forces or a third party's varies across these markets. Such use typically depends on several factors, including the nature of entry into the new market, the size of an opportunity and operational capabilities. Together with our collaborators, we market our products to healthcare providers, including physicians or their clinics, dialysis centers, hospitals and pharmacies.

In the United States, substantially all of our sales are to pharmaceutical wholesale distributors, which are the principal means of distributing our products to healthcare providers. We also market certain products through direct-to-consumer channels, including print, television and online media. For further discussion, see Government Regulation—Regulation in the United States—Regulation of Product Marketing and Promotion. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country.

Our product sales to three large wholesalers, AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc., each individually accounted for more than 10% of total revenues for each of the years 2020, 2019 and 2018. On a combined basis, these wholesalers accounted for 83%, 81% and 84% of worldwide gross revenues for 2020, 2019 and 2018, respectively. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

Our products are marketed around the world, with the United States being our largest market. The following chart shows our product sales by principal product, and the table below (dollar amounts in millions) shows product sales by geography for the years 2020, 2019 and 2018.

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	2020		2019		2018	
Product Sales by Geography:						
U.S.	$ 17,985	74 %	$ 16,531	74 %	$ 17,429	77 %
Ex-U.S.	6,255	26 %	5,673	26 %	5,104	23 %
Total	$ 24,240	100 %	$ 22,204	100 %	$ 22,533	100 %

ENBREL

We market ENBREL, a tumor necrosis factor blocker, primarily in the United States. ENBREL was launched in 1998 and is used primarily in indications for the treatment of adult patients with moderately to severely active rheumatoid arthritis, patients with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and patients with active psoriatic arthritis.

Prolia® (denosumab)

We market Prolia® primarily in the United States, Europe and the Asia Pacific region. Prolia® contains the same active ingredient as XGEVA® (denosumab) but is approved for different indications, patient populations, doses and frequencies of administration. Prolia® was launched in the United States and Europe in 2010. In the United States, it is used primarily in the indication for the treatment of postmenopausal women with osteoporosis at high risk of fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or in patients who have failed or are intolerant to other available osteoporosis therapy. In Europe, Prolia® is used primarily for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Neulasta® (pegfilgrastim)

We market Neulasta®, a pegylated protein based on the filgrastim molecule, primarily in the United States and Europe. Neulasta® was launched in 2002 and is used primarily in the indication to help reduce the chance of infection due to a low white blood cell count in patients with certain types of cancer (nonmyeloid) who receive anticancer medicines (chemotherapy) that can cause fever and a low blood cell count. In 2015, the Neulasta® Onpro® kit became available in the United States. The Neulasta® Onpro® kit provides physicians the opportunity to initiate the administration of Neulasta® on the same day as chemotherapy, with drug delivery of the recommended dose of Neulasta® at home the day after chemotherapy, thereby saving patients a trip back to the doctor.

Otezla®

We market Otezla®, a small molecule that inhibits phosphodiesterase 4 (PDE4), primarily in the United States and Europe. Otezla® was acquired from Bristol-Myers Squibb Company (BMS) in November 2019, post their acquisition of Celgene Corporation (Celgene). Otezla® is an oral therapy approved for the treatment of adult patients with moderate-to-severe plaque psoriasis for whom phototherapy or systemic therapy is appropriate, patients with active psoriatic arthritis and patients with oral ulcers associated with Behçet's disease. In Europe, Otezla® is approved for second-line use in the treatment of psoriatic arthritis and psoriasis.

XGEVA®

We market XGEVA® primarily in the United States and Europe. XGEVA® was launched in 2010 and is used primarily in the indication for prevention of skeletal-related events (SREs) (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumors and multiple myeloma.

Aranesp® (darbepoetin alfa)

We market Aranesp® primarily in the United States and Europe. It was launched in 2001 and is indicated to treat a lower-than-normal number of red blood cells (anemia) caused by chronic kidney disease (CKD) in both patients on dialysis and patients not on dialysis. Aranesp® is also indicated for the treatment of anemia due to concomitant myelosuppressive chemotherapy in certain patients with nonmyeloid malignancies and when chemotherapy will be used for at least two months after starting Aranesp®.

KYPROLIS®

We market KYPROLIS® primarily in the United States and Europe. KYPROLIS® was launched in 2012 and is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. It is also approved as a single agent for patients with relapsed or refractory multiple myeloma who have received one or more previous therapies. In September 2019, the CANDOR phase 3 study of KYPROLIS® in combination with dexamethasone and DARZALEX® (daratumumab) met its primary endpoint of PFS in patients with relapsed or refractory multiple myeloma. In August 2020, the FDA approved the expansion of the KYPROLIS® U.S. prescribing information to include its use in combination with dexamethasone and DARZALEX®.

Repatha® (evolocumab)

We market Repatha®, a proprotein convertase subtilisin/kexin type 9 (PCSK9), primarily in the United States and Europe. Repatha® was launched in 2015 and is indicated to reduce the risks of myocardial infarction, stroke and coronary revascularization in adults with established cardiovascular (CV) disease.

Other Marketed Products

We also market a number of other products in various markets worldwide, including Nplate® (romiplostim), Vectibix® (panitumumab), MVASI® (bevacizumab-awwb), Parsabiv® (etelcalcetide), EPOGEN® (epoetin alfa), KANJINTI® (trastuzumab-anns), BLINCYTO® (blinatumomab), Aimovig® (erenumab-aooe), EVENITY® (romosozumab-aqqg), AMGEVITA™ (adalimumab), Sensipar®/Mimpara® (cinacalcet), NEUPOGEN® (filgrastim), IMLYGIC® (talimogene laherparepvec), Corlanor® (ivabradine) and AVSOLA® (infliximab-axxq).

Patents

The following table lists our outstanding material patents for the indicated product by territory, general subject matter and latest expiry date. Certain of the European patents are the subjects of supplemental protection certificates that provide additional protection for the products in certain European countries beyond the dates listed in the table. See footnotes to the patent table below.

One or more patents with the same or earlier expiry dates may fall under the same general subject matter and are not listed separately.

Product	Territory	General subject matter	Expiration
Enbrel® (etanercept)	U.S.	Methods of treatment using aqueous formulations	6/8/2023
	U.S.	Formulations	10/19/2037
	U.S.	Fusion protein and pharmaceutical compositions	11/22/2028
	U.S.	DNA encoding fusion protein and methods of making fusion protein	4/24/2029
Prolia®/XGEVA® (denosumab)	U.S.	RANKL antibodies	9/17/2021
	U.S.	Methods of treatment	6/25/2022
	U.S.	Nucleic acids encoding RANKL antibodies and methods of producing RANKL antibodies	11/30/2023
	U.S.	RANKL antibodies, including sequences	2/19/2025
	Europe	RANKL antibodies, including epitope binding	2/23/2021
	Europe	RANKL antibodies, including sequences(1)	6/25/2022
Otezla® (apremilast)	U.S.	Compositions and compounds	2/16/2028
	U.S.	Crystalline form	12/9/2023
	U.S.	Methods of treatment	5/29/2034
	Europe	Compositions, compounds and methods of treatment(1)	3/20/2023
	Europe	Formulation	12/26/2032
Aranesp® (darbepoetin alfa)	U.S.	Glycosylation analogs of erythropoietin proteins	5/15/2024
KYPROLIS® (carfilzomib)	U.S.	Compositions and compounds	12/7/2027
	U.S.	Methods of treatment	4/14/2025
	U.S.	Methods of making	5/8/2033
	Europe	Compositions, compounds and methods of treatment(1)	12/7/2025
Repatha® (evolocumab)	U.S.	Antibodies(2)	10/25/2029
	U.S.	Methods of treatment	10/8/2030
	Europe	Compositions(1)	8/22/2028
	Europe	Methods of treatment	5/10/2032
	Europe	Formulation	5/3/2033
Nplate® (romiplostim)	U.S.	Thrombopoietic compounds	1/19/2022
	U.S.	Formulation	2/12/2028
	Europe	Thrombopoietic compounds(1)	10/22/2019
	Europe	Formulation	4/20/2027
Vectibix® (panitumumab)	Europe	Human monoclonal antibodies to epidermal growth factor receptor(1)	5/5/2018
Parsabiv® (etelcalcetide)	U.S.	Compound and pharmaceutical composition	2/7/2031
	U.S.	Formulation	6/27/2034
	U.S.	Methods of making	8/9/2035
	Europe	Compound and pharmaceutical composition(1)	7/29/2030
	Europe	Formulation	6/27/2034
BLINCYTO® (blinatumomab)	U.S.	Pharmaceutical compositions and bifunctional polypeptides	4/6/2030
	U.S.	Method of administration	9/28/2027
	Europe	Bifunctional polypeptides(1)	11/26/2024
	Europe	Method of administration	11/6/2029
Aimovig® (erenumab-aooe)	U.S.	CGRP receptor antibodies(2)	11/9/2031
	U.S.	Methods of treatment	4/22/2036
	Europe	CGRP receptor antibodies(1)	12/18/2029
	Europe	Methods of treatment	8/10/2035
EVENITY® (romosozumab-aqqg)	U.S.	Antibodies(2)	4/25/2026
	U.S.	Methods of treatment(2)	1/11/2029
	U.S.	Formulation and methods of using formulation	5/11/2031
	Europe	Antibodies(1)	4/28/2026
	Europe	Methods of treatment	4/18/2032
	Europe	Formulation and methods of using formulation	5/11/2031
IMLYGIC® (talimogene laherparepvec)	U.S.	Compositions	11/23/2025
	U.S.	Method of treatment	3/27/2022
	Europe	Composition and uses(1)	3/27/2022

CGRP = calcitonin gene-related peptide, RANKL = receptor activator of nuclear factor kappa-B ligand

(1) A European patent with this subject matter may also be entitled to supplemental protection in one or more countries in Europe, and the length of any such extension will vary by country. For example, supplementary protection certificates have been issued related to the indicated products for patents in at least the following countries:

- denosumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2025
- carfilzomib — France, Germany, Italy and Spain, expiring in 2030
- romiplostim — France, Germany, Italy, Spain and the United Kingdom, expiring in 2024
- panitumumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2022
- evolocumab — France and Spain, expiring in 2030
- etelcalcetide — France and Italy, expiring in 2031
- blinatumomab — France, Italy and Spain, expiring in 2029
- erenumab — France, Italy and Spain, expiring in 2033
- talimogene laherparepvec — Spain, expiring in 2026; France, Germany, Italy and the United Kingdom, expiring in 2027
- romosozumab — Italy, expiring in 2031
- apremilast — Italy and Spain, expiring in 2028

(2) A patent with this subject matter may be entitled to patent term extension in the United States.

Competition

We operate in a highly competitive environment. A number of our marketed products are indicated for disease areas in which other products or treatments are currently available or are being pursued by our competitors through research and development (R&D) activities. Additionally, some competitor-marketed products target the same genetic pathways as our recently launched marketed products or are currently in development. This competition could impact the pricing and market share of our products. We continue to pursue ways of increasing the value of our medicines through innovations during their life cycles, which can include expanding the disease areas for which our products are indicated and finding new methods to make the delivery of our medicines easier and less costly. Such activities can offer important opportunities for differentiation. For example, we market the Neulasta® Onpro® kit, which provides physicians the opportunity to initiate the administration of the recommended dose of Neulasta® on the same day as chemotherapy, with drug delivery at home the day after chemotherapy, thereby saving patients a trip back to the doctor. We plan to continue pursuing innovation efforts to strengthen our competitive position. Such position may be based on, among other things, safety, efficacy, reliability, availability, patient convenience, delivery devices, price, reimbursement, access to and timing of market entry and patent position and expiration.

Certain of the existing patents on our principal products have expired, and we face new and increasing competition, including from biosimilars and generics. A biosimilar is another version of a biological product for which marketing approval is sought or has been obtained based on a demonstration that it is "highly similar" to the original reference product. We expect that the adverse impact on our originator-product sales from biosimilar competition will reflect current trends and actual results given similar conditions. We also believe that when multiple biosimilar versions of one of our originator products get approved and launched, competition could intensify more rapidly, leading to net price declines for both reference and biosimilar products, resulting in a greater impact on our products' sales. In the United States, companies have now launched biosimilar versions of EPOGEN®, NEUPOGEN® and Neulasta® and have approved biosimilars for ENBREL. See also Government Regulation—Regulation in the United States—Approval of Biosimilars. Although we expect competitor biosimilars to compete on price, we believe many patients, providers and payers will continue to place high value on the reputation, reliability and safety of our products. As additional biosimilar competitors come to market, we will leverage our global experience versus both branded and biosimilar competition.

We also have our own biosimilar products both in the United States and outside of U.S. markets that are competing against branded and biosimilar versions of our competitors' products. In 2019, Amgen launched MVASI®, a biosimilar to Avastin® (bevacizumab), and KANJINTI®, a biosimilar to Herceptin® (trastuzumab), in the United States; and AMGEVITA™, a biosimilar to Humira® (adalimumab) in Europe. We have also received FDA approval for AMJEVITA™ (adalimumab-atto), a biosimilar to Humira®. In 2020, we launched AVSOLA®, a biosimilar to Remicade® (infliximab), and in January 2021, we launched RIABNI™, a biosimilar for Rituxan® (rituximab). We

expect additional biosimilar competition against both our branded and biosimilar products in the future across all markets.

In addition, although most of our products are biologics, some are small molecule products. Because the FDA approval process permits generic manufacturers to rely on the safety and efficacy data of the innovator product rather than having to conduct their own costly and time-consuming clinical trials, generic manufacturers can often develop and market their competing versions of our small molecule products at much lower prices. For example, following loss of exclusivity of patents directed to cinacalcet, the active ingredient in our small molecule calcimimetic Sensipar®, we lost a significant share of the market and corresponding revenues in a very short period of time. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

The introduction of new products, the development of new processes or technologies by competitors or the emergence of new information about existing products may result (i) in increased competition for our marketed products, even for those protected by patents and/or (ii) in reductions in the prices we receive from selling our products. In addition, the development of new treatment options or standards of care may reduce the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates. (As used in this document, the term *clinical trials* may include prospective clinical trials, observational studies, registries and other studies.) See Item 1A. Risk Factors—*Our products face substantial competition* and Item 1A. Risk Factors—*We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future*.

The following table reflects our significant competitors and is not exhaustive.

Product	Territory	Competitor-marketed product	Competitors
ENBREL	U.S. & Canada	REMICADE®*	Janssen Biotech, Inc. (Janssen)[1]
	U.S. & Canada	HUMIRA®	AbbVie Inc. (AbbVie)
	U.S. & Europe	Xeljanz®	Pfizer Inc.
	U.S. & Canada	RINVOQ®	AbbVie
Prolia®	U.S. & Europe	Alendronate, raloxifene and zoledronate generics	Various
Neulasta®[2]	U.S.	UDENYCA®	Coherus BioSciences, Inc.
	U.S.	Fulphila®	Mylan Institutional Inc.
	U.S. & Europe	Filgrastim biosimilars	Various
Otezla®	U.S. & Europe	HUMIRA®[3]†	AbbVie
	U.S. & Europe	Cosentyx®[3]	Novartis Pharma AG (Novartis)
	U.S. & Europe	Taltz®[3]	Eli Lilly and Company (Lilly)
	U.S. & Europe	Tremfya®[3]	Janssen
	U.S. & Europe	Skyrizi®[3]	AbbVie
	U.S. & Europe	Methotrexate generics[3]	Various
XGEVA®	U.S. & Europe	Zoledronate generics	Various
Aranesp®	U.S.	PROCRIT®[4]	Janssen[1]
	U.S. & Europe	Epoetin alfa biosimilars	Various
KYPROLIS®[5]	U.S.	VELCADE®	Millennium Pharmaceuticals, Inc.[6]
	U.S. & Europe	REVLIMID®	Celgene[7]
	U.S.	POMALYST®	Celgene[7]
	U.S.	DARZALEX®	Janssen[1]
Repatha®	U.S. & Europe	PRALUENT®	Regeneron Pharmaceuticals, Inc. Sanofi

* Approved biosimilars available.

† Approved biosimilars available in Europe.

(1) A subsidiary of Johnson & Johnson (J&J).

(2) Other biosimilars under regulatory review in the United States and Europe.

(3) Dermatology only.

(4) PROCRIT® competes with Aranesp® in supportive cancer care and predialysis settings.

(5) KYPROLIS® is facing increased competition from several recently approved products.

(6) A subsidiary of Takeda Pharmaceutical Company Limited.

(7) A subsidiary of BMS.

Reimbursement

Sales of our principal products are dependent on the availability and extent of coverage and reimbursement from third-party payers. In many markets around the world, these payers, including government health systems, private health insurers and other organizations, remain focused on reducing the cost of healthcare; and their efforts have intensified as a result of rising healthcare costs, economic pressures and broader challenges generated by the

COVID-19 pandemic. Drugs remain heavily scrutinized for cost containment. As a result, payers are becoming more restrictive regarding the use of biopharmaceutical products and are scrutinizing the prices of these products while requiring a higher level of clinical evidence to support the benefits such products bring to patients and the broader healthcare system. These pressures are intensified when our products are subject to competition, including from biosimilars.

In the United States, healthcare providers and other entities such as pharmacies and pharmacy benefit managers (PBMs) are reimbursed for covered services and products they deliver through both private-payer and government healthcare programs such as Medicare and Medicaid. We provide negotiated rebates to healthcare providers, private payers, government payers and PBMs. In addition, we are required to (i) provide rebates or discounts on our products that are reimbursed through certain government programs, including Medicare and Medicaid, and (ii) provide discounts to qualifying healthcare providers under the federal 340B Drug Pricing Program.

Both private and government payers use formularies to manage access and utilization of drugs. A drug's inclusion and favorable positioning on a formulary are essential to ensure patients have access to a particular drug. Even when access is available, some patients abandon their prescriptions for economic reasons. Payers continue to institute cost reduction and containment measures that lower drug utilization and/or spending altogether and/or shift a greater portion of the costs to patients. Such measures include, but are not limited to, more-limited benefit plan designs, higher patient co-pays or coinsurance obligations, limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs), stricter utilization management criteria before a patient may get access to a drug, higher-tier formulary placement that increases the level of patient out-of-pocket costs and formulary exclusion, which effectively encourages patients and providers to seek alternative treatments or pay 100% of the cost of a drug. The use of such measures by PBMs and insurers has continued to intensify and has thereby limited Amgen product usage and sales. Furthermore, during the past few years, many PBMs and insurers have consolidated, resulting in a smaller number of PBMs and insurers overseeing a large portion of total covered lives in the United States. As a result, PBMs and insurers have greater market power and negotiating leverage to mandate stricter utilization criteria and/or exclude drugs from their formularies in favor of competitor drugs or alternative treatments. In highly competitive treatment markets such as the markets for ENBREL, Otezla®, Repatha® and Aimovig®, PBMs are also able to exert negotiating leverage by requiring incremental rebates from manufacturers in order for them to gain and/or maintain their formulary position.

In addition to market actions taken by private and government payers in the United States, policy makers from both of the major U.S. political parties are pursuing policies to lower drug costs. Potential policies cover a wide range of areas, including allowing the importation of drugs from other countries; instituting international reference pricing (IRP) schemes, which would set the prices of certain drugs based on those available in other countries; establishing caps on price increases based on inflation metrics; increasing transparency on drug pricing; and using third-party value assessments to determine drug prices. Examples of such policies include the previous Administration's November 2020 interim final rule, which attempts to institute most favored nation (MFN) IRP in Medicare Part B and final rule instituting rebate reform in Medicare Part D. Both of these rules are being challenged in court and therefore have not yet been implemented. The direction of drug pricing policy reforms remains unclear at this time.

In many countries outside the United States, government-sponsored healthcare systems are the primary payers for drugs and biologics. With increasing budgetary constraints and/or difficulty in understanding the value of medicines, governments and payers in many countries are applying a variety of measures to exert downward price pressure. These measures can include mandatory price controls, price referencing, therapeutic-reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage and government-mandated price cuts. In this regard, many countries have health technology assessment organizations that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies; and these organizations are expanding in both established and emerging markets. Many countries also limit coverage to populations narrower than those specified on our product labels or impose volume caps to limit utilization. We expect that countries will continue taking aggressive actions to seek to reduce expenditures on drugs and biologics. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

The dynamics and developments discussed above serve to create pressure on the pricing and potential usage of our products and the industry. Given the diverse interests in play between payers, biopharmaceutical manufacturers, policy makers, healthcare providers and independent organizations, if and whether the parties involved can achieve alignment on the matters discussed above remain unclear, and the outcome of any such alignment is difficult to predict. We remain focused on pricing our products responsibly and delivering breakthrough treatments for unmet medical needs. Amgen is committed to working with the entire healthcare community to ensure continued innovation and to facilitate patient access to needed medicines. We do this by:

- investing billions of dollars annually in R&D;
- developing more affordable therapeutic choices in the form of high-quality and reliably supplied biosimilars;
- pricing our medicines to reflect the value they provide;
- partnering with payers to share risk and accountability for health outcomes;
- providing patient support and education programs;
- helping patients in financial need access our medicines; and
- working with policy makers, patients and other stakeholders to establish a sustainable healthcare system with access to affordable care and where patients and their healthcare professionals are the primary decision makers.

See Item 1A. Risk Factors—*Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures may affect our profitability* and Item 1A. Risk Factors—*Guidelines and recommendations published by various organizations can reduce the use of our products.*

Manufacturing, Distribution and Raw Materials

Manufacturing

We believe we are a leader in the manufacture of biologics and that our manufacturing capabilities represent a competitive advantage. The products we manufacture consist of both biologics and small molecule drugs. The majority of our products are biologics that are produced in living cells and that are inherently complex due to naturally occurring molecular variations. Highly specialized knowledge and extensive process and product characterization are required to transform laboratory-scale processes into reproducible commercial manufacturing processes. Further, our expertise in the manufacture of biologics positions us well for leadership in the global biosimilars market. For additional information regarding manufacturing facilities, see Item 2. Properties.

Our internal manufacturing network has commercial production capabilities for bulk manufacturing, formulation, fill, finish, tableting and device assembly. These activities are performed within the United States and its territories in our Puerto Rico, Rhode Island and California facilities as well as internationally in our Ireland, Netherlands and Singapore facilities. In addition, we use third-party contract manufacturers to supplement the capacity or capability of our commercial manufacturing network.

To support our clinical trials, we manufacture product candidates primarily at our California facilities. We also use third-party contract manufacturers to supplement the capacity or capability of our overall clinical manufacturing network.

See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

Distribution

We operate distribution centers in Puerto Rico, Kentucky, California and the Netherlands for worldwide distribution of the majority of our commercial and clinical products. We also use third-party distributors to supplement distribution of our products worldwide.

Other

In addition to the manufacturing and distribution activities noted above, each of our manufacturing locations includes key manufacturing support functions such as quality control, process development, engineering, procurement, production scheduling and warehousing. Certain of those manufacturing and distribution activities are highly regulated by the FDA as well as international regulatory agencies. See Government Regulation—Regulation in the United States—Regulation of Manufacturing Standards.

Manufacturing Initiatives

We have multiple ongoing initiatives that are designed to extend our manufacturing advantage by optimizing our manufacturing network and/or by mitigating risks while continuing to ensure adequate supply of our products.

For example, our licensed next-generation biomanufacturing plant operating in Singapore incorporates multiple innovative technologies into a single facility and was built in half the construction time and at approximately half the operating cost of a traditional plant. Next-generation biomanufacturing plants require smaller manufacturing footprints and offer greater environmental benefits, including reduced consumption of water and energy and lower levels of carbon emissions. Within such plants, the equipment is portable and smaller, and some components are disposable, which provides greater flexibility and speed when manufacturing different medicines simultaneously. This eliminates the otherwise costly and complex retrofitting inherent in standard plants and enables Amgen to respond to changing demands for its medicines with increased agility, ultimately increasing the speed at which a medicine can become available for patients. The Singapore site also has a plant that has been approved to produce small molecule drugs for commercial manufacturing.

In July 2018, we broke ground for our newest next-generation biomanufacturing plant at our West Greenwich, Rhode Island, campus. Construction on this new plant, the first of its kind in the United States, is complete. Upon approval by the FDA and global regulatory authorities, this plant will expand our capacity to manufacture certain products for U.S. and global markets.

In 2019, we initiated projects to expand our manufacturing capabilities in Thousand Oaks, California, as well as at contract manufacturers. These investments will initially support clinical manufacturing but in the future may also be leveraged for commercial manufacturing.

In September 2020, we entered into an arrangement with Lilly to manufacture Lilly's potential COVID-19 therapies. For 2021—and, potentially, through 2022—we expect to allocate a portion of our manufacturing capacity to support this production. Additionally, starting in 2021, we will initiate projects that will expand our manufacturing capacity to enable supply of products and product candidates. These projects will employ new technologies that are being developed by Amgen that are anticipated to allow further optimization of our manufacturing network and processes.

See Item 1A. Risk Factors—*Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

Raw Materials and Medical Devices

Certain raw materials, medical devices (including companion diagnostics) and components necessary for the commercial and/or clinical manufacturing of our products are provided by and are the proprietary products of unaffiliated third-party suppliers, certain of which may be our only sources for such materials. We currently attempt to manage the risk associated with such suppliers by means of inventory management, relationship management and evaluation of alternative sources when feasible. We also monitor the financial condition of certain suppliers and their ability to supply our needs. See Item 1A. Risk Factors—*We rely on third-party suppliers for certain of our raw materials, medical devices and components.*

We perform various procedures to help authenticate the sources of raw materials, including intermediary materials used in the manufacture of our products, which include verification of the country of origin. The procedures are incorporated into the manufacturing processes we and our third-party contract manufacturers perform.

To better ensure supply, Amgen has a risk mitigation strategy that uses a combination of methods, including multiple sources or backup inventory of critical raw materials. In response to COVID-19, we continue to closely monitor our inventory levels and have taken additional measures to mitigate against raw material supply interruption as part of our ongoing business continuity efforts. See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

Government Regulation

Regulation by government authorities in the United States and other countries is a significant factor in the production and marketing of our products and our ongoing R&D activities. To clinically test, manufacture and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards

established by various regulatory bodies. Compliance with these standards is complex, and failure to comply with any of these standards can result in significant implications. See Item 1A. Risk Factors for a discussion of factors, including global regulatory implications, that can adversely impact our development and marketing of commercial products.

Regulation in the United States

In the United States, the Public Health Service Act; the Federal Food, Drug, and Cosmetic Act (FDCA); and the regulations promulgated thereunder as well as other federal and state statutes and regulations govern, among other things, the production, research, development, testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising, promotion and distribution of our products in addition to the reporting of certain payments and other transfers of value to healthcare professionals and teaching hospitals.

Clinical Development and Product Approval. Drug development in our industry is complex, challenging and risky, and failure rates are high. Product development cycles are typically very long—approximately 10 to 15 years from discovery to market. A potential new medicine must undergo many years of preclinical and clinical testing to establish its safety and efficacy for use in humans at appropriate dosing levels and with an acceptable risk–benefit profile. We continue to work toward reducing cycle times by applying our expertise in human genetics and innovation in technology, clinical trials and real-world evidence.

After laboratory analysis and preclinical testing in animals, we file an Investigational New Drug Application (IND) with the FDA to begin human testing. Typically, we undertake an FDA-designated three-phase human clinical testing program.

- In phase 1, we conduct small clinical trials to investigate the safety and proper dose ranges of our product candidates in a small number of human subjects.
- In phase 2, we conduct clinical trials to investigate side-effect profiles and the efficacy of our product candidates in a patient population larger than phase 1 but still relatively small, who have the disease or condition under study.
- In phase 3, we conduct clinical trials to investigate the short- and long-term safety and efficacy of our product candidates, compared to commonly used treatments, in a large number of patients who have the disease or condition under study.

The FDA monitors the progress of each trial conducted under an IND and may, at its discretion, reevaluate, alter, suspend or terminate the testing based on the data accumulated to that point and the FDA's risk–benefit assessment with regard to the patients enrolled in the trial. The results of preclinical and clinical trials are submitted to the FDA in the form of either a Biologics License Application for biologic products or a NDA for small molecule products. We are not permitted to market or promote a new product until the FDA has approved our marketing application.

Approval of Biosimilars. The Affordable Care Act (ACA) authorized the FDA to approve biosimilars via a separate, abbreviated pathway. The pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on the nonclinical-trial and clinical-trial data of an originator product to which the biosimilar has been demonstrated to be "highly similar" and to have no clinically meaningful differences in terms of safety, purity and potency. The relevance of demonstrating "similarity" is that in many cases, biosimilars can be brought to market without conducting the full suite of clinical trials typically required of originators, because risk–benefit has previously been established. To preserve incentives for future innovation, the law establishes a period of exclusivity for originators' products, which in general prohibits biosimilars from gaining FDA approval based in part on reliance on or reference to the originator's data in their application to the FDA for 12 years after initial FDA approval of the originator product. The law does not change the duration of patents granted on biologic products. As part of the implementation of the abbreviated approval pathway for biosimilars, the FDA released a number of guidance documents, some of which remain in draft form.

Regulation of Product Marketing and Promotion. The FDA regulates the marketing and promotion of drug products. Our product promotions for approved product indications must comply with the statutory standards of the FDCA and the FDA's implemented regulations and guidance. The FDA's review of marketing and promotional activities encompasses but is not limited to direct-to-consumer advertising, healthcare-provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA may also review industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. The FDA may take enforcement action against a company for promoting unapproved uses of a product or for other violations of the FDA's advertising and labeling laws and regulations. Enforcement action may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or

other corrective communications to healthcare professionals. Failure to comply with the FDA's regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators. Additionally, as described below, such failure may lead to additional liability under U.S. healthcare fraud and abuse laws.

Regulation of Manufacturing Standards. The FDA regulates and inspects the equipment, facilities, laboratories and processes used in the manufacturing and testing of products prior to granting approval to market products. If after receiving approval from the FDA we make a material change in manufacturing equipment, location or process, additional regulatory review may be required. We also must adhere to current Good Manufacturing Practice regulations and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA conducts regular, periodic visits to reinspect our equipment, facilities, laboratories and processes following an initial approval.

Regulation of Combination Products. Combination products are defined by the FDA as products composed of two or more regulated components (e.g., a biologic and/or drug and a device). Biologics/drugs and devices each have their own regulatory requirements, and combination products may have additional requirements. A number of our marketed products meet this definition and are regulated under this framework, and we expect that a number of our pipeline product candidates will be evaluated for regulatory approval under this framework as well.

Regulation outside the United States

In European Union (EU) countries as well as in Switzerland, Canada, Australia and Japan, regulatory requirements and approval processes are similar in principle to those in the United States.

In the EU, there are currently two potential tracks for seeking marketing approval for a product not authorized in any EU member state: a decentralized procedure and a centralized procedure. In the *decentralized procedure*, identical applications for marketing authorization are submitted simultaneously to the national regulatory agencies. Regulatory review is led by one member state (the reference-member state), and its assessment—based on safety, quality and efficacy—is reviewed and approved (assuming there are no concerns that the product poses a serious risk to public health) by the other member states from which the applicant is seeking approval (the concerned-member states). The decentralized procedure leads to a series of single national approvals in all relevant countries. In the *centralized procedure*, which is required of all products derived from biotechnology, a company submits a single MAA to the EMA, which conducts an evaluation of the dossier, drawing upon its scientific resources across Europe. If the drug product is proven to fulfill requirements for quality, safety and efficacy, the EMA's Committee for Medicinal Products of Human Use (CHMP) adopts a positive opinion, which is transmitted to the European Commission (EC) for final decision on granting of the marketing authorization. Even though the EC generally follows the CHMP's opinion, it is not bound to do so. Subsequent commercialization is enabled by country-by-country reimbursement approval.

In the EU, biosimilars are approved under a specialized pathway of the centralized procedure. As with the U.S. pathway, an applicant seeks and obtains regulatory approval for a biosimilar once the data exclusivity period for the original reference product has expired, relying in part on the data submitted for the originator product together with data evidencing that the biosimilar is "highly similar" in terms of quality, safety and efficacy to the original reference product authorized in the European Economic Area.

As a result of the United Kingdom's decision to leave the EU, the EMA in March 2019 relocated to Amsterdam. The United Kingdom officially left the EU in January 2020, and in December 2020, a new trade deal was agreed that starts to clarify how U.K. medicines will be independently supervised and where continued collaborations and recognitions can be expected. Amgen continues to monitor future negotiations to ensure no interruption in the supervision, regulation or supply of medicines in the United Kingdom and Europe.

Other countries such as Russia, Turkey and those in Latin America and the Middle East have review processes and data requirements similar to those of the EU and in some cases can rely on prior marketing approval from U.S. or EU regulatory authorities. The regulatory process in these countries may include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements.

In Asia Pacific, a number of countries such as China, Japan, South Korea and Taiwan may require local clinical-trial data for bridging purposes as part of the drug registration process in addition to global clinical trials, which can add to overall drug development and registration timelines. In most of the Asian markets, registration timelines depend on marketing approval in the United States or the EU. In some markets in Asia, such as China, Indonesia and Thailand, the regulatory timelines can be less predictable. The regulatory process may also include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements. Countries such as Australia and Japan have more-mature systems that would allow for submissions under more-competitive time frames. Regarding biosimilars, several of these countries have pathways to register biosimilars

(e.g., Australia, India, Singapore, South Korea and Taiwan), and biosimilar products are already present on the markets (e.g., Australia and South Korea).

In some countries, such as Japan and those in the EU, medical devices may be subject to regulatory regimes whereby manufacturers must establish that their medical devices conform to essential requirements set out in the law for the particular device category. For example, in the EU, with limited exceptions, medical devices placed on the market must bear the Conformité Européenne marking to indicate their conformity with legal requirements.

Postapproval Phase

After approval, we continue to monitor adverse events and product complaints reported following the use of our products through routine postmarketing surveillance and studies when applicable. We report such events to the appropriate regulatory agencies as required by local regulations for individual cases and aggregate reports. We proactively monitor (according to good pharmacovigilance practices) and ensure the implementation of signal detection, assessment and the communication of adverse events that may be associated with the use of our products. We also proactively monitor product complaints through our quality systems, which includes assessing our drug delivery devices for device complaints, adverse events and malfunctions. We may also be required by regulatory agencies to conduct further clinical trials on our marketed products as a condition of their approval or to provide additional information on safety and efficacy. Health regulators, including the FDA, have authority to mandate labeling changes to products at any point in a product's life cycle based on new safety information or as part of an evolving label change to a particular class of products.

Health regulators, including the FDA, also have authority, before or after approval, to require a company to implement a risk management program for a product to ensure that the benefits of the drug outweigh the risks. Each risk management program is unique and varies depending on the specific factors required. In the United States, a risk management program is known as a risk evaluation and mitigation strategy (REMS), and we currently have REMSs for Prolia®, Nplate® and BLINCYTO®.

Other Regulation

We are also subject to various laws pertaining to healthcare fraud and abuse, including antikickback laws and false-claims laws. Antikickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for or to induce the referral of business, including the purchase or prescribing of a particular drug that is reimbursed by a state or federal program. False-claims laws prohibit knowingly and willingly presenting or causing to be presented for payment to third-party payers (including Medicare and Medicaid) any claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as by the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). Liability under the false-claims laws may also arise when a violation of certain laws or regulations related to the underlying product (e.g., violations regarding improper promotional activity or unlawful payments) contributes to the submission of a false claim.

In 2012, Amgen entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health & Human Services (HHS), which was formally closed out in August 2018. On April 25, 2019, we entered into a settlement agreement with the U.S. Department of Justice (DOJ) and the OIG of the HHS to settle certain allegations related to our support of independent charitable organizations that provide patients with financial assistance to access their medicines. Additionally, we entered into a corporate integrity agreement that requires us to maintain a corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that in the future, our practices might be further challenged under antikickback or similar laws.

The U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA arguably includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anticorruption laws and/or regulations. Failure by our employees, agents, contractors, vendors, licensees, partners or collaborators to comply with the FCPA and other anticorruption laws and/or regulations could result in significant civil or criminal penalties.

We are subject to various laws and regulations globally regarding privacy and data protection. These laws and regulations involve the collection, storage, handling, use, disclosure, transfer and security of personal data. The

legislative and regulatory environments regarding privacy and data protection are continually evolving and developing, as these issues are the subjects of increasing amounts of attention in countries globally. For example, we are subject to the EU's General Data Protection Regulation (GDPR), which became effective on May 25, 2018, and the California Consumer Privacy Act of 2018, which became effective on January 1, 2020. Other jurisdictions where we operate have enacted or proposed similar legislation and/or regulations. Failure to comply with these laws could result in significant penalties.

Our business has been and will continue to be subject to various other U.S. and foreign laws, rules and regulations. See Reimbursement section above.

Research and Development and Selected Product Candidates

We focus our R&D on novel human therapeutics for the treatment of serious illness. We capitalize on our strengths in human genetics, novel biology and protein engineering. We leverage our biologic expertise and take a modality-independent approach to R&D. And we use cutting-edge science and technology to study subtle biological mechanisms in search of therapies that will improve the lives of those who suffer from diseases.

Our discovery research programs may therefore yield targets that lead to the development of human therapeutics delivered as large molecules, small molecules, other combination modalities or new modalities. We have reshaped our portfolio and have increasingly focused our efforts on human genetics when possible to enhance the likelihood of success.

In response to the COVID-19 pandemic, we managed our clinical development on a case-by-case basis. Patients who were already enrolled in studies continued to receive study drug, including through direct-to-patient shipments. For studies that had the potential for significant benefit in a serious or life-threatening condition and when site resources enabled new patients to be enrolled safely and monitored closely, we continued enrollment. For clinical trials experiencing uncertainty with regard to the trial sites' ability to ensure subject safety or data integrity at that time, we temporarily paused enrollment. We remain focused on supporting our active clinical sites in providing care for these patients and providing investigational drug supply. To date, the majority of clinical trials that were paused at the onset of the pandemic to ensure subject safety or data integrity have resumed. Study enrollments were affected the most in the second quarter of 2020 and by the end of the year resumed to prepandemic levels, although COVID-19 infection rates and related vaccination activities may impact future patient enrollment. We continuously monitor and reevaluate the status of studies, pausing when uncertainty arises with regard to the trial sites' ability to ensure safety or data integrity. We remain focused on supporting our active clinical sites in providing care for these patients and in providing investigational drug supply. In addition, our R&D organization is supporting efforts to combat the COVID-19 pandemic in a number of ways, including by (i) working to support production of therapeutic antibodies that could diminish the impact of COVID-19 on patients, (ii) joining a public–private partnership between leading companies in our industry and U.S. government health agencies to develop a strategy for a coordinated research response and (iii) participating in platform studies to investigate treatments in adult patients hospitalized with severe COVID-19 infections.

For the years ended December 31, 2020, 2019 and 2018, our R&D expenses were $4.2 billion, $4.1 billion and $3.7 billion, respectively.

We have major R&D centers in Thousand Oaks and San Francisco, California; Iceland; and the United Kingdom, as well as smaller research centers and development facilities globally. See Item 2. Properties.

Our clinical trial activities are conducted by both our internal staff and third-party contract clinical trial service providers. To increase the number of patients available for enrollment in our clinical trials, we have opened clinical sites and will continue opening clinical sites and enrolling patients in a number of geographic locations. See Government Regulation—Regulation in the United States—Clinical Development and Product Approval for a discussion of government regulation over clinical development. Also see Item 1A. Risk Factors—*We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.*

Some of our competitors are actively engaged in R&D in areas in which we have products or in which we are developing product candidates or new indications for existing products. For example, we compete with other clinical trials for eligible patients, which may limit the number of available patients who meet the criteria for certain clinical trials. The competitive marketplace for our product candidates is greatly dependent on the timing of entry into the market. Early entry may have important advantages in gaining product acceptance, thereby contributing to a product's eventual success and profitability. Accordingly, we expect that in some cases, the relative speed with which we can develop products, complete clinical testing, receive regulatory approval and supply commercial quantities of a product to the market will be important to our competitive position.

In addition to product candidates and marketed products generated from our internal R&D efforts, we acquire companies, acquire and license certain product and R&D technology rights and establish R&D arrangements with

third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. In pursuing these R&D arrangements and licensing or acquisition activities, we face competition from other pharmaceutical and biotechnology companies that also seek to license or acquire technologies, product candidates or marketed products from those entities performing the R&D.

The following table shows a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 2, 2021, unless otherwise indicated. Additional product candidate information can be found on our website at www.amgen.com. (The website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.) The information in this section does not include other, nonregistrational clinical trials that we may conduct for purposes other than for submission to regulatory agencies for their approval of a new product indication.

We may conduct nonregistrational clinical trials for various reasons, including to evaluate real-world outcomes or to collect additional safety information with regard to the use of our products.

Molecule	Disease/condition
Phase 3 programs	
EVENITY®	Male osteoporosis
KYPROLIS®	Weekly dosing for relapsed multiple myeloma
Nplate®	Chemotherapy-induced thrombocytopenia
Otezla®	COVID-19 Genital psoriasis Mild-to-moderate psoriasis
Repatha®	Cardiovascular disease
RIABNI™	Rheumatoid arthritis
Sotorasib	NSCLC with *KRAS G12C* mutations
Tezepelumab	Severe asthma
ABP 654	Psoriasis, psoriatic arthritis and Crohn's disease
ABP 938	Neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy
ABP 959	Paroxysmal nocturnal hemoglobinuria (PNH)
Phase 2 programs	
Olpasiran (formerly AMG 890)	Cardiovascular disease
Rozibafusp alfa (formerly AMG 570)	Systemic lupus erythematosus
Sotorasib	Advanced colorectal cancer Other solid tumors with *KRAS G12C* mutations
Tezepelumab	Chronic obstructive pulmonary disease
AMG 714/PRV-015	Celiac disease
Phase 1 programs	
Efavaleukin alfa (formerly AMG 592)	Inflammatory diseases
AMG 119	Small-cell lung cancer
AMG 133	Obesity
AMG 160	Prostate cancer
AMG 171	Obesity
AMG 176	Hematologic malignancies
AMG 199	Metastatic gastric and gastroesophageal junction cancer
AMG 256	Solid tumors
AMG 330	Acute myeloid leukemia
AMG 397	Hematologic malignancies
AMG 404	Solid tumors
AMG 427	Acute myeloid leukemia
AMG 506	Solid tumors
AMG 509	Prostate cancer
AMG 594[(1)]	Cardiovascular disease
AMG 650	Solid tumors
AMG 673	Acute myeloid leukemia
AMG 701	Multiple myeloma
AMG 757	Small-cell lung cancer
AMG 910	Gastric and gastroesophageal junction cancer

(1) In November 2020, we provided notice to Cytokinetics of termination of our collaboration effective May 20, 2021 and of our intention to transition to them the development and commercialization rights for omecamtiv mecarbil and AMG 594.

Phase 3	Clinical trials investigate the short- and long-term safety and efficacy of our product candidates, compared to commonly used treatments, in a large number of patients who have the disease or condition under study.
Phase 2	Clinical trials investigate side-effect profiles and efficacy of product candidates in a larger patient population than phase 1, but still relatively small, who have the disease or condition under study.
Phase 1	Clinical trials investigate the safety and proper dose ranges of product candidates in a small number of human subjects.

Phase 3 Product Candidate Program Changes

As of February 12, 2020, we had 14 phase 3 programs. As of February 2, 2021, we had 13 phase 3 programs, as regulatory approvals were received for three programs, two programs initiated phase 3 studies, two programs initiated biosimilarity studies, one concluded and one termination and transition of program to Cytokinetics. These changes are set forth in the following table.

Molecule	Disease/condition	Program change
KYPROLIS®	Multiple myeloma	Approved by the FDA
Otezla®	Behçet's disease	Approved by the FDA
	COVID-19	Initiated phase 3 study
RIABNI™	Non-Hodgkin's lymphoma	Approved by the FDA
Sotorasib	NSCLC	Initiated phase 3 study
ABP 654	Psoriasis, psoriatic arthritis and Crohn's disease	Initiated biosimilarity study
ABP 938	Neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy	Initiated biosimilarity study
IMLYGIC®	Metastatic melanoma	Concluded
Omecamtiv mecarbil	Chronic heart failure	Concluded; no longer pursuing our marketing application with the FDA and EC[1]

[1] In November 2020, we provided notice to Cytokinetics of termination of our collaboration effective May 20, 2021 and of our intention to transition to them the development and commercialization rights for omecamtiv mecarbil and AMG 594.

Based on our approval pathway that did not require phase 3 study, in January 2021, Nplate® was approved by the FDA for treatment of hematopoietic syndrome of acute radiation syndrome.

Phase 3 Product Candidate Patent Information

The following table describes our composition-of-matter patents that have been issued thus far for our product candidates in phase 3 development that have yet to be approved for any indication in the United States or the EU. Patents for products already approved for one or more indications in the United States or the EU but that are currently undergoing phase 3 clinical trials for additional indications have been previously described. See Marketing, Distribution and Selected Marketed Products—Patents.

Molecule	Territory	General subject matter	Estimated expiration*
Sotorasib	U.S.	Compound	2038
Tezepelumab	U.S.	Polypeptides	2029
	Europe	Polypeptides	2028

* Patent expiration estimates are based on issued patents, which may be challenged, invalidated or circumvented by competitors. The patent expiration estimates do not include any term adjustments, extensions or supplemental protection certificates that may be obtained in the future and thereby extend these dates. Corresponding patent applications are pending in other jurisdictions. Additional patents may be filed or issued and may provide additional exclusivity for the product candidate or its use.

Phases 3 and 2 Program Descriptions

The following provides additional information about selected product candidates that have advanced into human clinical trials.

EVENITY®

EVENITY® is a humanized monoclonal antibody that inhibits the action of sclerostin. It is being evaluated as a treatment for male osteoporosis. EVENITY® is being developed in collaboration with UCB.

IMLYGIC®

IMLYGIC® is an oncolytic immunotherapy derived from herpes simplex virus type 1 (HSV-1). A Phase 3 study evaluating IMLYGIC® in combination with pembrolizumab (KEYTRUDA®) versus pembrolizumab alone for treatment of unresectable stage IIIB to IVM1c melanoma was stopped for futility after an interim analysis by the Data Monitoring Committee. No new safety signals were observed.

KYPROLIS®

KYPROLIS® is a small molecule proteasome inhibitor. It is being investigated for weekly dosing in combinations with lenalidomide and dexamethasone for relapsed multiple myeloma.

In August 2020, the FDA approved the expansion of the KYPROLIS® U.S. prescribing information to include its use in combination with DARZALEX® plus dexamethasone in two dosing regimens—once weekly and twice weekly—for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three previous lines of therapy.

Nplate®

Nplate® is a thrombopoietin receptor agonist. It is being investigated in phase 3 studies for chemotherapy-induced thrombocytopenia.

In December, the European Commission approved an expanded indication for use in adult patients who have had immune thrombocytopenia for 12 months or less and who have had an insufficient response to corticosteroids or immunoglobulins.

As noted above, the FDA has approved Nplate® for the treatment of hematopoietic syndrome of acute radiation syndrome.[1]

OLPASIRAN

Olpasiran is a small interfering RNA (siRNA) that lowers lipoprotein(a), also known as Lp(a). It is being investigated in phase 2 for the treatment of atherosclerotic CV disease.

Otezla®

Otezla® is a small molecule that inhibits PDE4. It is being investigated in phase 3 studies for the treatment of patients with mild-to-moderate plaque psoriasis, patients with moderate-to-severe genital psoriasis and, in collaboration with some of the members of the COVID R&D Alliance, adult patients hospitalized with COVID-19.

In May 2020, we announced positive results from the ADVANCE trial, a phase 3, multicenter, randomized, placebo-controlled, double-blind study to assess the efficacy of Otezla® in adults with mild-to-moderate plaque psoriasis. The study showed that oral Otezla® 30 mg twice daily achieved a statistically significant improvement, compared with placebo, in the primary endpoint of the sPGA response at week 16. In addition, the week 16 secondary endpoints of achieving at least 75% improvement from baseline in the percent of affected body surface area (BSA), change in BSA total score from baseline and change in Psoriasis Area and Severity Index (PASI) total score from baseline were each also statistically significant for the treatment effect of Otezla® compared with placebo.

Repatha®

Repatha® is a human monoclonal antibody that inhibits PCSK9. It is being investigated as a treatment for atherosclerotic CV disease in high-risk patients with high low-density lipoprotein cholesterol (LDL-C) without prior heart attack or stroke.

In March 2020, we announced positive results from the BEIJERINCK study evaluating the efficacy and safety of Repatha® in patients who are human immunodeficiency virus-positive (HIV+) and have high LDL-C despite stable background lipid-lowering therapy. The study demonstrated that treatment with Repatha® significantly reduced LDL-C.

RIABNI™

RIABNI™, a biosimilar candidate to Rituxan®/MabThera® (rituximab), is an anti-CD20 monoclonal antibody. It is being investigated in a phase 3 study for treatment of rheumatoid arthritis. The reference-product primary conditions are non-Hodgkin's lymphoma, chronic lymphocytic leukemia and rheumatoid arthritis.

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[1] Funding and execution of the pivotal study was provided by the National Institute of Allergy and Infectious Diseases (NIAID) and the Priority Review regulatory submission was conducted in partnership with the Biomedical Advanced Research and Development Authority (BARDA).

In December 2020, we announced that the FDA had approved RIABNI™ for the treatment of adult patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, granulomatosis with polyangiitis (Wegener's granulomatosis), and microscopic polyangiitis. RIABNI™ launched in the United States in January 2021.

Rozibafusp alfa

Rozibafusp alfa is a novel bispecific antibody-peptide conjugate that simultaneously blocks the B lymphocyte stimulator (BAFF) and inducible costimulatory ligand (ICOSL) activity. It is being investigated as a treatment for systemic lupus erythematosus.

Sotorasib

Sotorasib is a KRAS *G12C* small molecule inhibitor. It is being investigated as a treatment for a variety of solid tumors, including NSCLC, colorectal cancer and other solid tumor cancers.

In December 2020, we announced that the FDA had granted Breakthrough Therapy designation for sotorasib for the treatment of patients with locally advanced or metastatic NSCLC with *KRAS G12C* mutation as determined by an FDA-approved test, following at least one prior systemic therapy. The sotorasib application is being reviewed under the FDA's RTOR pilot program, which aims to explore a more efficient review process that ensures safe and effective treatments are made available to patients as early as possible.

In January 2021, we announced phase 2 results from the CodeBreaK 100 clinical study, evaluating sotorasib in 126 patients with *KRAS G12C-mutant* advanced NSCLC, who had failed a median of two prior lines of anticancer therapies (immunotherapy and/or chemotherapy). Sotorasib demonstrated a confirmed ORR (primary end point) and disease control rate of 37.1% and 80.6%, respectively, a median duration of response of 10 months and median progression-free survival of 6.8 months. Patients were treated with sotorasib 960 mg once daily orally.

Tezepelumab

Tezepelumab is a human monoclonal antibody that inhibits the action of thymic stromal lymphopoietin. It is being evaluated in phase 3 as a treatment for severe asthma. It is also being investigated in phase 2 for chronic obstructive pulmonary disease. Tezepelumab is being developed jointly in collaboration with AstraZeneca.

In November 2020, we announced positive results from the registrational phase 3 NAVIGATOR trial, in which the investigational medicine tezepelumab demonstrated a statistically significant reduction in exacerbations compared to placebo in patients with severe asthma. The NAVIGATOR trial met the primary endpoint with tezepelumab added to SoC, demonstrating a statistically significant and clinically meaningful reduction compared to placebo plus SoC in the AAER over 52 weeks in the overall patient population. SoC consisted of medium- or high-dose ICS plus at least one additional controller medication with or without OCS.

In December 2020, we announced that the SOURCE trial had not met the primary endpoint of a statistically significant reduction in the daily OCS dose, without loss of asthma control, with tezepelumab compared to placebo. The results of this trial have no impact on our submission plans.

AMG 714/PRV-015

AMG 714/PRV-015 is a human monoclonal antibody that binds to interleukin-15. It is being investigated for the treatment of celiac disease and is being developed in collaboration with Provention Bio.

ABP 654

ABP 654, a biosimilar candidate to STELARA® (ustekinumab), is a monoclonal antibody that inhibits interleukin-12 and interleukin-23. It is being investigated in a phase 3 study for biosimilarity to STELARA®. The reference-product primary conditions are psoriasis, psoriatic arthritis and Crohn's disease.

ABP 938

ABP 938, a biosimilar candidate to EYLEA® (aflibercept), is a vascular endothelial growth factor receptor (VEGFR) Fc fusion protein. It is being investigated in a phase 3 study for neovascular (wet) age-related macular degeneration (AMD). The reference-product primary conditions are wet AMD, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy.

ABP 959

ABP 959, a biosimilar candidate to SOLIRIS® (eculizumab), is a monoclonal antibody that specifically binds to the complement protein C5. It is being investigated in a phase 3 study for PNH. The reference-product primary conditions are PNH and atypical hemolytic uremic syndrome (aHUS).

Business Relationships

From time to time, we enter into business relationships, including joint ventures and collaborative arrangements, for the R&D, manufacture and/or commercialization of products and/or product candidates. In addition, we acquire product and R&D technology rights and establish R&D collaborations with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed-product base. These arrangements generally provide for nonrefundable, upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. The activities under these collaboration agreements are performed with no guarantee of either technological or commercial success, and each is unique in nature.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require counterparties to execute confidentiality agreements upon commencement of a business relationship with us. However, others could either develop independently the same or similar information or unlawfully obtain access to our information.

BeiGene, Ltd.

On January 2, 2020, we acquired a 20.5% stake in BeiGene, Ltd. (BeiGene) for approximately $2.8 billion in cash as part of a collaboration to expand our oncology presence in China. Under the collaboration, BeiGene commenced selling XGEVA® and will commercialize KYPROLIS® and BLINCYTO® in China, and Amgen will share profits and losses equally during the initial product-specific commercialization periods; thereafter, product rights may revert to Amgen, and Amgen will pay royalties to BeiGene on sales in China of such products for a specified period.

In addition, we will jointly develop a portion of our oncology portfolio with BeiGene sharing in global R&D costs by providing cash and development services up to $1.25 billion. Upon regulatory approval, BeiGene will assume commercialization rights in China for a specified period, and Amgen and BeiGene will share profits equally until certain of these product rights revert to Amgen. Upon return of the product rights, Amgen will pay royalties to BeiGene on sales in China for a specified period. For product sales outside of China, Amgen will also pay BeiGene royalties.

Novartis

We are in a collaboration with Novartis to jointly develop and commercialize Aimovig®. In the United States, Amgen and Novartis jointly develop and collaborate on the commercialization of Aimovig®. Amgen, as the principal, recognizes product sales of Aimovig® in the United States, shares U.S. commercialization costs with Novartis and pays Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig®. Novartis pays Amgen double-digit royalties on net sales of the product in the Novartis-exclusive territories and funds a portion of global R&D expenses. In addition, Novartis will make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds are achieved with respect to Aimovig® in the United States. Amgen manufactures and supplies Aimovig® worldwide.

We are currently involved in litigation with Novartis over our collaboration agreements for the development and commercialization of Aimovig®. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Bayer HealthCare LLC

We are in a licensing arrangement with Bayer HealthCare LLC (Bayer) for Nexavar®. In February 2020, we amended the terms of our agreement with Bayer, which transferred all of our operational responsibilities outside the United States to Bayer, including commercial and medical affairs activities. Prior to the amendment of the agreement, we shared equally in the profits outside the United States, excluding Japan. In lieu of this profit share, Bayer now pays us a royalty on sales of Nexavar® at a percentage rate in the low 30s. The rights to develop and

market Nexavar® in Japan are reserved to Bayer. In the United States, Bayer pays us a royalty on sales of Nexavar® at a percentage rate in the high 30s.

DaVita Inc.

In January 2017, we entered into a six-year supply agreement with DaVita Inc. (DaVita), which superseded the previously existing, seven-year supply agreement that commenced in 2012. Pursuant to the 2017 agreement, we supply EPOGEN® and Aranesp® in amounts necessary to meet specified annual percentages of DaVita's and its affiliates' requirements for erythropoiesis-stimulating agents (ESAs) used in providing dialysis services in the United States and Puerto Rico. Such percentages vary during the term of the agreement, but in each year are at least 90%. The agreement expires in 2022. The agreement may be terminated by either party before expiration of its term in the event of certain breaches of the agreement by the other party.

For financial information concerning our significant collaborative arrangements, see Part IV—Note 8, Collaborations, to the Consolidated Financial Statements.

Human Capital Resources

Amgen's approach to human capital resource management starts with our mission to serve patients. Our industry exists in a complex regulatory and reimbursement environment. The unique demands of our industry, together with the challenges of running an enterprise focused on the discovery, development, manufacture and commercialization of innovative medicines, require talent that is highly educated and/or has significant industry experience. Additionally, for certain key functions, we require specific scientific expertise to oversee and conduct R&D activities and the complex manufacturing requirements for biopharmaceutical products.

As of December 31, 2020, Amgen had approximately 24,300 staff members, and we have had relatively low global turnover rates. We consider our staff relations to be good; supported by our regular staff engagement assessments, with surveys on a wide range of topics (including engagement in the COVID-19 environment, diversity, inclusion and belonging and ethics). We discuss the results of these surveys with our Board of Directors.

Compensation, Benefits and Development

Our approach to employee compensation and benefits is designed to deliver cash, equity and benefit programs that are competitive with those offered by leading companies in the biotechnology and pharmaceutical industries to attract, motivate and retain talent with a focus on encouraging performance, promoting accountability and adherence to Company values and alignment with the interests of the Company's shareholders.

Our base pay program aims to compensate staff members relative to the value of the contributions of their role, which takes into account the skills, knowledge and abilities required to perform each position, as well as the experience brought to the job. We also provide annual incentive programs to reward our staff in alignment with achievement of Company-wide goals that are established annually and designed to drive aspects of our strategic priorities that support and advance our strategy across our Company. The majority of our staff members are also eligible for the grant of equity awards under our long-term incentive program that are designed to align the experience of these staff with that of our shareholders. All staff also participate in a regular performance measurement process that aligns pay to performance and through which staff receive performance and development feedback. To support the development of our staff, we provide a variety of programs, including leadership development programs, virtual instructor-led courses and self-paced learning options.

Our benefit programs are also generally broad-based, promote health and overall well-being and emphasize saving for retirement. All regular U.S. staff members are eligible to participate in the same core health and welfare and retirement savings plans. Other U.S. employee benefits include medical plans, dental plans, access to childcare, employee assistance programs, employee stock purchase plan, flexible spending accounts, life, long-term care and business travel accident insurance, short and long-term disability benefits, wellness benefits and work-life resources and referrals. Comparable programs and benefits are available globally, with the same health and well-being intent, consistent with statutory requirements.

Our Compensation and Management Development Committee provides oversight of our compensation plans, policies and programs.

Safety and Wellness and Our Response to COVID-19

Creating a safe and healthy workplace for our staff is a priority at Amgen. Our goal is to have a world class safety record through safety leadership, risk management practices and integrating safety throughout our business processes. To foster our safety culture, we implement a comprehensive safety program, driving to understand and mitigate the root cause of safety incidents and manage and control variability. We use leading indicators to assess the effectiveness of our safety programs and make course corrections as needed. Additionally, we perform formal executive management review of functional safety performance for Operations, Global Commercial Operations and R&D on a quarterly basis with a focus on identifying early signals and taking action to drive continuous improvement. Based on our 2019 performance, compared to a benchmark of twelve companies in the pharmaceutical industry, Amgen was in the quartile with the lowest injury rate.

In response to the COVID-19 pandemic and as part of our commitment to work to ensure the safety and well-being of our employees, we have activated our applicable business continuity plans, including having those of our employees who are able to work from home to do so since mid-March 2020. For employees returning to the workplace and the field, we have also taken additional safety measures, including implementing occupancy limits, restricting business travel, providing and requiring the use of personal protective equipment, temperature screening and COVID-19 testing to access our workplaces.

Our Corporate Responsibility and Compliance Committee provides general oversight of our safety programs and initiatives, while our Board of Directors, as a whole, has overseen our specific responses to the COVID-19 pandemic.

Diversity, Inclusion and Belonging

We believe that a diverse and inclusive culture fosters innovation, which supports our ability to serve patients. Further, we also believe our global presence is strengthened by having a workforce that reflects the diversity of the patients we serve. It is with these beliefs in mind that we have continued to strengthen and grow our culture of diversity, inclusion and belonging. Our internal efforts include, in 2019, establishing a Diversity, Inclusion and Belonging Council chaired by our Chief Executive Officer. In 2020, we implemented a global unconscious bias training program, and launched a portal devoted to diversity, inclusion and belonging that includes learning and resources. Further, we are leveraging our Employee Resource Groups (listed below) to represent and support the diversity of Amgen staff:

Employee Resource Groups	
Amgen Asian Association (AAA)	Amgen Black Employee Network (ABEN)
Ability Bettered through Leadership and Education (ABLE), a resource group for the physically or cognitively disabled	
Amgen Early Career Professionals (AECP)	Amgen Indian Subcontinent Network (AISN)
Amgen Latin Employee Network (ALEN)	Amgen LGBTQ and Allies Network (PRIDE)
Amgen Veterans Employees Network (AVEN)	Women Empowered to be Exceptional (WE2)
Women in Information Systems Enrichment (WISE)	

In areas of underrepresentation, we develop plans with a goal of bringing our representation in line with availability, and we also engage in outreach efforts to attract, retain and advance more women and minorities in our workforce. For example, we have worked to enhance our diverse candidate recruiting pool by developing relationships with organizations that can serve as a source of diverse candidates, such as the National Black MBA Association and National Sales Network, as well as historically black colleges and universities. Additionally, at the

end of 2020, we became a founding member of OneTen, a coalition of 35 of the world's largest, best-known companies, that aims to hire one million Black Americans (with a specific focus on those without four-year college degrees) into good-paying, family-sustaining jobs over the next ten years. Other examples of actions that we are taking in this area include investment and participation in Healthcare Businesswomen's Association (a global organization focused on development and business networking for women in healthcare) and the University of California, Los Angeles (UCLA) Anderson School of Management women's leadership program.

In an effort to provide additional transparency into the makeup of our workforce, we intend to disclose our 2020 Consolidated EEO-1 Report after our submission of the report to the U.S. Equal Employment Opportunity Commission.

Our Corporate Responsibility and Compliance Committee provides oversight of our policies, programs and initiatives focusing on workforce diversity and inclusion.

Information about Our Executive Officers

The executive officers of the Company as of February 8, 2021, are set forth below.

Mr. Robert A. Bradway, age 58, has served as a director of the Company since 2011 and Chairman of the Board of Directors since 2013. Mr. Bradway has been the Company's President since 2010 and Chief Executive Officer since 2012. From 2010 to 2012, Mr. Bradway served as the Company's President and Chief Operating Officer. Mr. Bradway joined the Company in 2006 as Vice President, Operations Strategy, and served as Executive Vice President and Chief Financial Officer from 2007 to 2010. Prior to joining the Company, Mr. Bradway was a Managing Director at Morgan Stanley in London, where, beginning in 2001, he had responsibility for the firm's banking department and corporate finance activities in Europe. Mr. Bradway has been a director of The Boeing Company, an aerospace company and manufacturer of commercial airplanes, defense, space and securities systems, since 2016. He has served on the board of trustees of the University of Southern California since 2014. From 2011 to 2017, Mr. Bradway was a director of Norfolk Southern Corporation, a transportation company.

Mr. Murdo Gordon, age 54, became Executive Vice President, Global Commercial Operations, in 2018. Prior to joining the Company, Mr. Gordon was Chief Commercial Officer at BMS from 2016 to 2018. Mr. Gordon served as Head of Worldwide Markets at BMS from 2015 to 2016. Prior to this, Mr. Gordon served in a variety of leadership roles at BMS for more than 25 years.

Mr. Jonathan P. Graham, age 60, became Executive Vice President, General Counsel and Secretary in 2019. Mr. Graham joined the Company in 2015. From 2015 to 2019, Mr. Graham was Senior Vice President, General Counsel and Secretary. Prior to joining Amgen, from 2006 to 2015, Mr. Graham was Senior Vice President and General Counsel at Danaher Corporation. From 2004 to 2006, Mr. Graham was Vice President, Litigation and Legal Policy, at General Electric Company (GE). Prior to GE, Mr. Graham was a partner at Williams & Connolly LLP.

Mr. Peter H. Griffith, age 62, became Executive Vice President and Chief Financial Officer in 2020. Mr. Griffith joined the Company in 2019 as Executive Vice President, Finance. Prior to joining Amgen, Mr. Griffith was President of Sherwood Canyon Group, LLC. From 1997 to 2019, Mr. Griffith was a partner at EY and served in a variety of senior leadership roles, with his last position being Global Vice Chair, Corporate Development. Prior to EY, Mr. Griffith was a Managing Director and head of the investment banking division of Wedbush Securities Inc.

Ms. Nancy A. Grygiel, age 53, became Senior Vice President and Chief Compliance Officer in 2020. Ms. Grygiel joined the Company in 2015. From 2016 to 2020, Ms. Grygiel was Vice President, Compliance. Prior to joining Amgen, from 2011 to 2015, Ms. Grygiel served as Vice President, Compliance, Corporate & International, at Allergan, Inc. (Allergan). Prior to Allergan, Ms. Grygiel held several management positions at Mylan Pharmaceuticals, Inc.

Ms. Lori A. Johnston, age 56, became Executive Vice President, Human Resources, in 2019. From 2016 to 2019, Ms. Johnston served as the Company's Senior Vice President, Human Resources. From 2012 to 2016, Ms. Johnston was Executive Vice President and Chief Administrative Officer of Celanese Corporation (Celanese). Prior to Celanese, Ms. Johnston served in a series of progressive leadership roles at Amgen from 2001 to 2012, with her last position being Vice President, Human Resources. Prior to joining the Company, Ms. Johnston held human resources and other positions at Dell Inc.

Mr. David A. Piacquad, age 64, became Senior Vice President, Business Development, in 2014. Mr. Piacquad joined the Company in 2010 and served as Vice President, Strategy and Corporate Development, until his appointment to the role of Vice President, Business Development, in 2014. Prior to joining the Company, from 2009 to 2010, Mr. Piacquad was Principal of David A. Piacquad Consulting LLC. From 2006 to 2009, Mr. Piacquad served as Senior Vice President, Business Development and Licensing, at Schering-Plough Corporation (Schering-Plough). Prior to Schering-Plough, Mr. Piacquad served in a series of leadership roles in finance and business development at J&J, with his last position being Vice President, Ventures and Business Development.

Dr. David M. Reese, age 58, became Executive Vice President, R&D, in 2018. Dr. Reese joined the Company in 2005 and has held leadership roles in development, medical sciences and discovery research. Dr. Reese was Senior Vice President, Translational Sciences and Oncology, from 2017 to 2018 and Senior Vice President, Translational Sciences, from 2015 to 2017. Prior to joining Amgen, Dr. Reese was director of Clinical Research at the Breast Cancer International Research Group from 2001 to 2003 and a cofounder, president and chief medical officer of Translational Oncology Research International, a not-for-profit academic clinical research organization, from 2003 to 2005. Dr. Reese previously served on the faculty at UCLA and the University of California, San Francisco.

Mr. Esteban Santos, age 53, became Executive Vice President, Operations, in 2016. Mr. Santos joined the Company in 2007 as Executive Director, Manufacturing Technologies. From 2008 to 2013, Mr. Santos held a number of Vice President roles at the Company in engineering, manufacturing, site operations and drug product. From 2013 to 2016, Mr. Santos was Senior Vice President, Manufacturing. Prior to joining the Company, Mr. Santos served as Site General Manager of J&J's Cordis operation in Puerto Rico. Prior to J&J, Mr. Santos held several management positions in GE's industrial and transportation businesses.

Geographic Area Financial Information

For financial information concerning the geographic areas in which we operate, see Part IV—Note 3, Revenues and Note 11, Property, plant and equipment, to the Consolidated Financial Statements.

Investor Information

Financial and other information about us is available on our website at www.amgen.com. We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with or furnish it to the U.S. Securities and Exchange Commission (SEC). In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected without charge at the SEC's website at www.sec.gov. (These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.)

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

SUMMARY

Risks Related to Economic Conditions and Operating a Global Business, Including During the COVID-19 Pandemic

- The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations.
- A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.
- Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.

Risks Related to Government Regulations and Third-Party Policies

- Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.
- Guidelines and recommendations published by various organizations can reduce the use of our products.
- The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability.
- Our business may be affected by litigation and government investigations.

Risks Related to Competition

- Our products face substantial competition and our product candidates are also likely to face substantial competition.
- Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.
- We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.
- Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively affect our business.

Risks Related to Research and Development

- We may not be able to develop commercial products despite significant investments in R&D.
- We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.
- Our current products and products in development cannot be sold without regulatory approval.
- Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.
- Some of our pharmaceutical pipeline and our commercial product sales rely on collaborations with third parties, which may adversely affect the development and sale of our products.
- Our efforts to collaborate with or acquire other companies, products, or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.

Risks Related to Operations

- We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.
- We rely on third-party suppliers for certain of our raw materials, medical devices and components.
- Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

General Risk Factors

- Global economic conditions may negatively affect us and may magnify certain risks that affect our business.
- Our stock price is volatile
- We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

RISKS RELATED TO ECONOMIC CONDITIONS AND OPERATING A GLOBAL BUSINESS, INCLUDING DURING THE COVID-19 PANDEMIC

The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations.

The novel coronavirus identified in late 2019, SARS-CoV-2, which causes the disease known as COVID-19, is an ongoing global pandemic that has resulted in public and governmental efforts to contain or slow the spread of the disease, including widespread shelter-in-place orders, social distancing interventions, quarantines, travel restrictions and various forms of operational shutdowns. The COVID-19 pandemic and the resulting measures implemented in response to the pandemic are adversely affecting, and is expected to continue to adversely affect, our business (including our R&D, clinical trials, operations, supply chains, distribution systems, product development and sales activities), the business activities of our suppliers, customers, third-party payers and our patients. See *Our current products and products in development cannot be sold without regulatory approval*, and see also *We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications*. Due to the pandemic and these measures and their effects, we have experienced, and expect to continue to experience, unpredictable reductions in demand for certain of our products, and in some cases, have experienced, and could continue to experience, unpredictable increases in demand for certain of our products.

Our clinical trials have been, and are expected to continue to be, adversely affected by the COVID-19 pandemic. We have clinical work ongoing at investigational sites across the globe. A number of clinical trial sites, including those in regions experiencing new or resurgent outbreaks of COVID-19, have restricted site visits and imposed restrictions on the initiation of new clinical trials and/or patient visits to protect both site staff and patients from possible COVID-19 exposure that has stopped or slowed clinical trial activities. In response to the safety concerns related to COVID-19, we have suspended, and will continue to suspend, enrollment and screening in clinical trials where sites are unable to perform clinical trial work due to COVID-19 or there is uncertainty around the ability of sites to ensure subject safety or data integrity. Further, the COVID-19 pandemic has adversely affected, and may continue to adversely affect, our ability to enroll or to continue to enroll certain required post-marketing studies, including pediatric studies. While many of our clinical trial activities have recommenced over the course of 2020, the initial disruption caused by the COVID-19 pandemic to our clinical trials and our clinical trial plans and timelines, and any similar future disruptions (including as a result of the current surge and lockdowns in numerous regions), may have a significant adverse effect on our product development and launches, and, in turn, on future product sales, business and results of operations. For example, to ensure patient safety we initially paused enrollment of our sotorasib Phase 1 combination cohort with Keytruda® and Phase 3 lung cancer study, and such interruptions in enrollment may ultimately affect the timeline of these or other studies. Additionally, while we are investing in research, collaborations and operational support to potentially develop and/or produce treatments for COVID-19, such activities may not result in therapeutic candidates, product approvals, successful production and/or significant commercial value being derived from potential COVID-19-related medicines.

As a result of the COVID-19 pandemic, we have experienced, and expect to continue to experience, regulatory delays, including delays in receiving regulatory advice, reviews of applications, or performance of inspections required for approvals. The pandemic may also result in greater regulatory uncertainty. For example, the FDA and the EMA have issued guidance to provide biopharmaceutical manufacturers greater flexibility in certain regulatory areas, including protocol deviations and adverse event reporting. However, such flexibility may result in greater uncertainty regarding the expectations of such health authorities in relation to this guidance. Additionally, there may be delays in ongoing or new patent office or patent proceedings in the United States or internationally that may delay the outcome of such proceedings. Such delays and disruptions could have a significant adverse effect on our product development and launches, product sales, business and results of operations.

In response to COVID-19, we have activated our applicable business continuity plans, including suspending U.S. in-person meetings and interactions with the healthcare community and professionals in a substantial number of states, suspending, as a general matter, all international business travel and the majority of domestic travel within the United States, and U.S. employees who are able to work from home have been doing so since mid-March 2020. Our ability to perform critical functions and maintain operations have been adversely affected and could continue to be adversely affected as a result of such workforce restrictions, and the COVID-19-related support programs we have put into place for our staff, suppliers and customers have increased, and are expected to continue to increase, our operating expenses and reduce the efficiency of our operations. Notwithstanding such support programs, the COVID-19 pandemic's effects on the health and availability of our workforce, as well as those of the third parties on which we rely, could have an adverse effect on our business. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to COVID-19, we may not be able to execute on our business strategy and our operations may be adversely affected. Additionally, disruptions in public and private infrastructure, including transportation and supply chains, have adversely affected, and continue to adversely affect, the efficiency of our business operations. Also, the transition of the majority of our workforce to a remote work environment in response to COVID-19, as well as that of our third-party service providers, have exacerbated certain risks to our business, including, but not limited to, those associated with an increased demand for information technology resources, increased risk of cybersecurity attacks (including social engineering attacks), and increased risk of unauthorized dissemination of sensitive personal information or our proprietary or confidential information. As the pandemic continues to progress, we have observed an increase in cybersecurity incidents, predominantly ransomware and social engineering attacks, experienced by our third-party service providers. Further, government entities have also been the subject of cyberattacks. The EMA disclosed in December 2020 that it had been the subject of a cyberattack that targeted and accessed third-party documents relating to regulatory submissions, and that such documents were published on the internet (some of which were manipulated prior to publication). Such third-party and governmental incidents have created the risk of the loss of availability and/or control of information (including information related to our clinical trials) important to the operation of our business. See *A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.* In the future, as the pandemic progresses and afterwards, we may experience significant adverse effects on our commercial and clinical manufacturing activities, our operations, and our cybersecurity, and our suppliers and vendors may also experience significant disruptions to their activities and operations on which we depend, as a result of these cybersecurity incidents.

Federal, state and local, and international governmental policies and initiatives designed to reduce the transmission of COVID-19 also have resulted in the cancellation or delay of diagnostic, elective, specialty and other procedures and appointments to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19. These measures and challenges will likely continue to varying degrees for the duration of the pandemic and have significantly reduced patient access to, and administration of, certain of our drugs. For example, Prolia® is a product requiring administration by a healthcare provider in doctors' offices or other healthcare settings that are affected by COVID-19. The U.S. label for Prolia® instructs healthcare professionals who discontinue Prolia® to transition the patient to an alternative antiresorptive, including oral treatments that do not require administration by a healthcare provider. Further, as a result of COVID-19, oncology patients, in consultation with their doctors, may be selecting less immunosuppressive therapies or therapies that do not require administration in a hospital setting, potentially adversely affecting certain of our products. Also, new patients are less likely to be diagnosed and/or to start therapeutics during the pandemic. Once the pandemic subsides, we anticipate there will be a substantial backlog of patients seeking appointments with physicians relating to a variety of medical conditions, and as a result, patients seeking treatment with certain of our products may have to navigate limited provider capacity, and this limited provider capacity could have a continued adverse effect on our sales following the opening up of various geographies and/or the end of the pandemic. Further, the effects of the COVID-19 pandemic may result in long-term shifts in preferences among healthcare professionals and patients toward treatments that do not require administration by healthcare professionals or visits to medical facilities.

The legislative and regulatory environment governing our businesses is dynamic and changing frequently in response to COVID-19. For example, the COVID-19 pandemic has resulted in increased interest in compulsory licenses, march-in rights or other governmental interventions, both in the United States and internationally, related to the procurement of drugs, such as the WHO's COVID-19 Technology Access Pool initiative, which provides an approach for sharing all intellectual property, information and clinical trial data necessary to enable generic drug manufacturing. *See Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation*. Further, the challenges of the pandemic have resulted in the exploration of signification legislation to address the need to supply medicines to address COVID-19. Pursuant to the declaration of a national emergency in the United States in March 2020 under the Stafford Act, state and local governments may request access to discounted pricing for certain items related to the COVID-19 response. The Coronavirus Aid, Relief and Economic Security (CARES) Act implements initiatives to provide advanced payments from Medicare to healthcare providers, clinics and physicians and to require Medicare plans to provide up to a 90-day supply of Part D drugs. However, despite such initiatives and government support, there may be adverse effects on the timing and collectability of our customer receivables as a result of the COVID-19 pandemic. See *Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively affect our business.* The COVID-19 pandemic has also resulted in a significant increase in unemployment and underemployment which may continue after the pandemic. Such a significant increase in unemployment or other disruptions in the labor market have led to a substantial reduction in disposable income and, in the U.S., access to healthcare insurance, including reductions in the commercially insured population that has led to growth (and is expected to continue to lead to growth) in Medicaid enrollment, which has adversely affected our product sales. See *Global economic conditions may negatively affect us and may magnify certain risks that affect our business*. Such reduction in healthcare insurance could be compounded by any full or partial repeal of the ACA by the U.S. Supreme Court. Further, globally, the substantial pressures placed on governmental and payor budgets as a result of the COVID-19 pandemic and the projected governmental budget shortfalls caused by significantly reduced economic activity during and potentially after the COVID-19 pandemic, together with the long-term impact from the pressures on healthcare systems, may result in greater and continued downward price pressure on biopharmaceutical products and increased intensity of stakeholder negotiations across the biopharmaceutical value chain. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability.*

As the pandemic continues, and if conditions worsen or if the duration of the pandemic extends significantly, we expect to experience additional adverse effects on our operational and commercial activities, customer purchases and our collections of accounts receivable. It is unclear which adverse effects may be material, and it remains uncertain the degree to which these adverse effects would impact our future operational and commercial activities, customer purchases and our collections even if conditions begin to improve. There was a resurgence in COVID-19 infections in numerous jurisdictions in the autumn of 2020 and winter of 2020-2021, resulting in the reinstatement of stricter restrictions and shutdowns in a number of jurisdictions. It is expected that the pandemic will continue to ebb and flow, with different jurisdictions having higher levels of infections than others over the course of the pandemic. In addition to existing travel restrictions, jurisdictions may continue or reinstate border closures, impose or reimpose prolonged quarantines and further restrict travel and business activity, which could significantly affect our ability to support our operations and customers and the ability of our employees to get to their workplaces to discover, study, develop and produce our product candidates and products, disrupt the movement of our products through the supply chain, and prevent or discourage patients from seeking healthcare services and the administration of certain of our products. Further, in connection with the global outbreak and spread of COVID-19 and in an effort to increase the wider availability of needed medical products, we or our suppliers may elect to, or governments may require us or our suppliers to, allocate manufacturing capacity (for example pursuant to the U.S. Defense Production Act) in a way that adversely affects our regular operations, customer relationships and financial results. In the U.S., on January 21, 2021, President Biden issued an Executive Order instructing federal agencies to use all available legal authorities, including the Defense Production Act, to improve current and future pandemic response and biological threat preparedness. The rapid reallocation of resources for the treatment and prevention of COVID-19, including the production of COVID-19 vaccinations or related therapies, such as our agreement to contribute to the production of one of Lilly's potential COVID-19 antibody therapies, could also result in increased competition for, or reduced availability of, materials used in the manufacturing or distribution of our products. In addition, unpredictable increases in demand for certain of our products could exceed our capacity to meet such demand, which could adversely affect our financial results and customer relationships.

The COVID-19 pandemic and the volatile global economic conditions stemming from it may precipitate or amplify the other risks described in this "Risk Factors" section, which could materially adversely affect our business, operations and financial conditions and results. For example, if a natural disaster or other potentially disruptive event occurs concurrently with the COVID-19 pandemic, such disaster or event could deplete our inventory levels and we could experience a disruption to our manufacturing or ability to supply our products. Further, the global pandemic has exacerbated geopolitical tensions, and some countries, such as China, may be especially vulnerable to such dynamics. If relations between the United States and China or other governments deteriorates, our business and investments in China or other such markets may also be adversely affected. See *Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.*

The rapid development and fluidity of the pandemic preclude any prediction as to the ultimate effect of COVID-19 on us. The duration of the measures being taken by the authorities to mitigate against the spread of COVID-19 (including the distribution of vaccines), and the extent to which such measures are effective, if at all, remain highly uncertain. The magnitude and degree of COVID-19's adverse effect on our business (including our product development, product sales, operating results, and resulting cash flows) and financial condition will be driven by the severity and duration of the pandemic, the pandemic's effect on the United States and global economies and the timing, scope and effectiveness of federal, state, local and international governmental responses to the pandemic. If the spread continues at or near its current trajectory or mitigation continues to require similar levels of shelter-in-place and shut-down orders, any adverse effects of COVID-19 will likely grow and could be enduring and our business and financial position could be materially adversely affected.

A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.

To achieve our business objectives, we rely on sophisticated information technology systems, including software, mobile applications, cloud services and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or adversely affect our reputation.

Our information technology systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. Further, as the majority of our employees are working remotely, our reliance on our and third-party information technology systems has increased substantially and is expected to continue to increase. The complexity and interconnected nature of our systems makes them potentially vulnerable to breakdown or other service interruptions. Our systems are also subject to frequent cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity and are becoming increasingly difficult to detect. Such attacks could include the use of harmful and virulent malware, including ransomware or other denials of service, that can be deployed through various means, including the software supply chain, e-mail, malicious websites and/or the use of social engineering. Attacks such as those experienced by governmental entities (including those that approve and/or regulate our products, such as the EMA) and other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access or protect important data, and could have a material adverse effect on our ability to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and/or distributing our products. For example, in 2017, a pharmaceutical company experienced a cyberattack involving virulent malware that significantly disrupted its operations, including its research and sales operations and the production of some of its medicines and vaccines. As a result of the cyberattack, its orders and sales for certain products in certain markets were negatively affected. In December 2020, SolarWinds Corporation, a leading provider of software for monitoring and managing information technology infrastructure, disclosed that it had suffered a cybersecurity incident whereby attackers had inserted malicious code into legitimate software updates for its products that were installed by myriad private and government customers, enabling the attackers to access a backdoor to such systems. See *The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations* for a discussion of the cyberattack on the EMA.

Our systems also contain and utilize a high volume of sensitive data, including intellectual property, trade secrets, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials

and/or personal information belonging to us, our staff, our patients, customers and/or other parties. In some cases, we utilize third-party service providers to process, store, manage or transmit such data, which may increase our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) or lapses by employees, service providers (including providers of information technology-specific services), nation states (including groups associated with or supported by foreign intelligence agencies), organized crime organizations, “hacktivists” or others, create risks that our sensitive data may be exposed to unauthorized persons, our competitors, or the public.

Domestic and global government regulators, our business partners, suppliers with whom we do business, companies that provide us or our partners with business services and companies we may acquire may face similar risks, and security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. For example, in 2019, two vendors that perform testing and analytical services that we use in developing and manufacturing our products have experienced cyberattacks, and in April and September of 2020, vendors that provide us with information technology services and clinical data services, respectively, each experienced ransomware attacks. Each of these incidents required us to disconnect our systems from those vendors' systems. While we were able to reconnect our systems following restoration of these vendor's capabilities without significantly affecting product availability, a more extended service outage affecting these or other vendors, particularly where such vendor is the single source from which we obtain the services, could have a material adverse effect on our business or results of operations. In addition, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers and patients.

Although we have experienced system breakdowns, attacks and information security breaches, we do not believe such breakdowns, attacks and breaches have had a material adverse effect on our business or results of operations. We continue to invest in the monitoring, protection and resilience of our critical and/or sensitive data and systems. However, there can be no assurances that our efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks, and/or breaches of our systems that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in material financial, legal, business or reputational harm to us or negatively affect our stock price. While we maintain cyber-liability insurance, our insurance is not sufficient to cover us against all losses that could potentially result from a service interruption, breach of our systems or loss of our critical or sensitive data.

We are also subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and developing and the subject of significant attention globally. For example, we are subject to the EU's GDPR, which became effective in May 2018, and the California Consumer Privacy Act of 2018, which became effective in January 2020, both of which provide for substantial penalties for non-compliance. Other jurisdictions where we operate have enacted or proposed similar legislation and/or regulations. Failure to comply with these current and future laws could result in significant penalties and could have a material adverse effect on our business and results of operations.

Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.

As we continue our expansion efforts in emerging markets around the world, through acquisitions and licensing transactions as well as through the development and introduction, both independently and through collaborations such as our collaboration with BeiGene, of our products in new markets, we face numerous risks to our business. There is no guarantee that our efforts and strategies to expand sales in emerging markets will succeed. Our international business, including in China and emerging market countries, may be especially vulnerable to periods of global and local political, legal, regulatory and financial instability, including issues of geopolitical relations, the imposition of international sanctions in response to certain state actions and/or sovereign debt issues. We may also be required to increase our reliance on third-party agents and unfamiliar operations and arrangements including those previously utilized by companies we partner with or acquire in emerging markets. See *We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications*. Our expansion efforts in China and emerging markets around the world is dependent upon the establishment of an environment that is predictable, navigable and supportive of biopharmaceutical innovation, sustained access for our products and limited pricing controls. For example, China continues to strengthen regulations on the collection, use and transmission of Chinese human genetic resources, and has expanded regulations on the conduct of biotechnology R&D activities in China. Our applications to the Human Genetic Resources Administration of China (HGRAC) seeking approval to conduct clinical trials in China are delayed pending further guidance from HGRAC. Our international operations and business may also be subject to less protective intellectual property or other applicable laws, diverse data privacy and protection requirements, changing tax laws and tariffs, trade restrictions or other barriers designed to protect industry in the home country against foreign competition, far-reaching antibribery and anticorruption laws and regulations and/or evolving legal and regulatory environments.

As we expand internationally, we are subject to fluctuations in foreign currency exchange rates relative to the U.S. dollar. While we have a program in place that is designed to reduce our exposure to foreign currency exchange rate fluctuations through foreign currency hedging arrangements, our hedging efforts do not completely offset the effect of these fluctuations on our revenues and earnings. In addition, we have a number of financial instruments referencing the London Interbank Offered Rate (LIBOR). On July 27, 2017, the U.K Financial Conduct Authority, which regulates LIBOR, announced that it will no longer require banks to submit rates for the calculation of LIBOR to the LIBOR administrator after 2021, and it is anticipated that LIBOR will be phased out and replaced by 2023. In March 2020, the Financial Accounting Standards Board issued a new accounting standard to ease the financial burdens of the expected market transition from LIBOR and other interbank offered rates to alternative reference rates. While various replacement reference rates have been proposed, an alternative reference rate to LIBOR has not yet been widely adopted, and the specific mechanisms to replace LIBOR in our existing LIBOR-linked financial instruments have not been finalized. As such, the replacement of LIBOR could have an adverse effect on the market for, or value of, our LIBOR-linked financial instruments. See Part IV, Note 1, Summary of significant accounting policies—Recent accounting pronouncements. We are also subject to the economic and political uncertainties stemming from the United Kingdom's exit from the EU, commonly referred to as "Brexit," which occurred on January 31, 2020. While our manufacturing and packaging activities take place largely outside the United Kingdom, minimizing the need to make costly and significant changes to those operations, we have nevertheless been working to put in place contingency plans to attempt to mitigate the effects of Brexit on us. Overall, the legal and operational challenges of our international business operations, along with government controls, the challenges of attracting and retaining qualified personnel and obtaining and/or maintaining necessary regulatory or pricing approvals of our products, may result in material adverse effects on our international product sales, business and results of operations.

RISKS RELATED TO GOVERNMENT REGULATIONS AND THIRD-PARTY POLICIES

Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.

Sales of our products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers continue to pursue initiatives to manage drug utilization and contain costs. These payers are increasingly focused on the effectiveness, benefits and costs of similar treatments, which could result in lower reimbursement rates for our products or narrower populations for whom payers will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payer dynamics, have limited, and are likely to continue to limit, our ability to set or adjust the price of our products based on their value, which could have a material adverse effect on our business. In the United States, particularly over the past few years, a number of legislative and regulatory proposals have been introduced in an attempt to lower drug prices. These include proposals that would allow the U.S. government to negotiate drug price directly, limit drug reimbursement based on prices abroad or permit importation of drugs from Canada. Proposals focused on drug pricing are likely to continue to be proposed and may be adopted and implemented in some form.

—Changing U.S. federal coverage and reimbursement policies and practices have affected and may continue to affect access to, pricing and sales of our products

A substantial portion of our U.S. business relies on reimbursement from federal government healthcare programs and commercial insurance plans regulated by federal and state governments. See Item 1. Business—Reimbursement. Our business has been and will continue to be affected by legislative actions changing U.S. federal reimbursement policy. Since late 2018, Congressional focus on drug pricing has increased, placing our industry under greater Congressional scrutiny. For example, in early 2019, the chair of the House Oversight and Reform Committee sent letters to twelve different biopharmaceutical manufacturers, including Amgen, seeking documents and detailed information about such companies' drug pricing practices. Subsequently, in the fall of 2020, the House Oversight and Reform Committee released staff reports and held hearings with executives from six biopharmaceutical manufacturers, including Amgen, about their companies' drug pricing practices. Also, between 2019 and 2020, a number of other Congressional committees held hearings and evaluated proposed legislation on drug-pricing and payment policy. For example, in 2019, the Senate Finance Committee advanced a bill that would, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and/or D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries, and require higher/additional manufacturer discounts in Medicare Part D. Additionally, in late 2019, a drug-pricing bill, H.R. 3, passed the House of Representatives, which would, among other things, enable direct price negotiations by the federal government on certain drugs (with the maximum price paid by Medicare capped by prices derived from an international index), includes a penalty for failing to reach agreement with the government, and requires that manufacturers offer these negotiated prices to other payers. We expect H.R. 3, or some similar proposed legislation, to be debated by Congress this year. Additional legislative or regulatory proposals have been introduced by members of Congress and the prior Administration that, if enacted and implemented in whole or in part, could also affect access to and sales of our products, including, but not limited to, proposals to allow importation of prescription medications from Canada or other countries and to set Medicare payment rates using international price referencing. Further, in mid-2020, the prior Administration announced a number of Executive Orders intended to reduce the cost of biopharmaceuticals for patients, including a MFN policy for Medicare Parts B and D, under which the HHS was directed to take steps to implement payment models that set Medicare purchase prices based on the lowest price available in economically comparable countries for certain Part B and Part D medicines. In September 2020, in response to the corresponding Executive Order, HHS released a final rule to allow states (or other nonfederal government entities) to submit proposals to the FDA allowing for the importation of certain nonbiologic prescription drugs from Canada. Currently, the rule is being challenged by litigation, however, should such litigation be unsuccessful and should the Secretary of HHS authorize state proposals for importation, this rule could allow the importation of Canadian versions of certain of Amgen's products (including Otezla®), that could have a material adverse effect on Amgen's business. Further, in November 2020, also in response to the corresponding Executive Order, HHS released an interim final rule to implement the MFN pricing approach. If implemented, the MFN rule would set the reimbursement rate for 50 Medicare Part B drugs (including our products, such as Prolia®, XGEVA®, KYPROLIS®, Neulasta®, Nplate®, EPOGEN® and Aranesp®) equal to the lowest adjusted price for such products of the 22 Organization for Economic Co-operation and Development (OECD) nations. Lawsuits have been filed by certain trade groups challenging the implementation of this MFN rule based on, among other things, procedural defects. Late in 2020, in the case filed by the Biotechnology Industry Organization and others, the U.S. District Court for the Northern District of California issued a preliminary injunction preventing the rule from taking effect nationwide, pending the government's completion of required administrative procedures. The case was subsequently stayed by the court and the parties were ordered to file a joint status report by April 23, 2021. Another case, filed by the Pharmaceutical Research and Manufacturers of America and others in the U.S. District Court for the District of Maryland, was also stayed. Notwithstanding these stays, the MFN rule's approach to drug pricing and other similar approaches, remain of interest. Further, despite the change in Administration, we expect continued significant focus on healthcare and similar drug pricing proposals, including proposals similar to the MFN rule, for the foreseeable future.

Our business has been, and is expected to continue to be, affected by changes in U.S. federal reimbursement policy resulting from federal regulations and federal demonstration projects. For example, the previous Administration released a drug pricing blueprint in 2018 which introduced an array of policy ideas intended to increase competition, improve the negotiating power of the federal government, reduce drug prices and lower patient out-of-pocket costs with the potential to significantly affect, whether individually or collectively, our industry. Such policy ideas included, but were not limited to, moving coverage and reimbursement for Medicare Part B drugs into

Medicare Part D and instituting a competitive acquisition program for Part B drugs in which competing third-party vendors take on the financial risk of acquiring drugs and billing Medicare.

Also, over the past three years, federal agencies, including the Centers for Medicare & Medicaid Services (CMS), announced a number of recommendations, policies, proposals and demonstration projects to implement various elements of the drug pricing blueprint. CMS is the federal agency responsible for administering Medicare and overseeing state Medicaid programs and Health Insurance Marketplaces and has substantial power to implement policy changes or demonstration projects that can quickly and significantly affect how drugs, including our products, are covered and reimbursed. CMS issued guidance to allow certain Medicare plans offered by private insurance companies to require that patients receiving Medicare Part B drugs first try a drug preferred by the plan before covering another therapy (Step Therapy) and lowered reimbursement rates for new Medicare Part B drugs. Further, HHS issued a final rule under Medicare Part D revising the regulations under the federal antikickback statute to encourage PBMs to use rebates received from biopharmaceutical manufacturers to reduce patient cost-sharing at the point of sale. Changes to the regulations will be phased-in beginning on March 22, 2021, with all changes effective as of January 1, 2023. However, there are numerous logistical hurdles to overcome before such rule can be effectively implemented and it is unclear how PBMs will change their business practices in response. Furthermore, a trade association representing PBMs recently filed litigation challenging this HHS final rule. Given these uncertainties, it remains unclear when any anticipated benefits to patients will materialize. The incoming Administration also could develop and seek to advance a range of policy proposals that could impact U.S. federal reimbursement policy for drugs and biologics.

CMS policy changes and demonstration projects to test new care, delivery and payment models can significantly affect how drugs, including our products, are covered and reimbursed. In end-stage renal disease (ESRD), CMS uses bundled payment rates. Between 2018 and 2020, Sensipar® and Parsabiv®, our calcimimetics that are used in dialysis clinics, were eligible for temporary drug add-on payment adjustments (TDAPA) to the bundled rate. In November 2020, CMS released its final rule ending the TDAPA for calcimimetics and adjusting ESRD Prospective Payment System bundled rates on January 1, 2021 by $9.93 per dialysis treatment for calcimimetics, and we expect the sales of our calcimimetics to be materially adversely affected by this rule change. Additionally, CMS created a new mandatory payment model effective January 1, 2021 focused on encouraging greater use of home dialysis and kidney transplants for ESRD patients that could result in changes to treatment of dialysis patients, including reduction of the use of our ESAs. Further, back in November 2019, CMS announced additional voluntary payment models for nephrologists and dialysis facility partners that also seek to encourage home dialysis and preemptive transplantation through increased risk sharing, but due to COVID-19, the start date of such programs has been pushed back to April 1, 2021. CMS has also solicited suggestions regarding other potential care models. In 2016, CMS initiated the Oncology Care Model demonstration, which provides participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare costs without negatively affecting the efficacy of care, that has been extended by one year (to 2022) due to COVID-19. We believe the Oncology Care Model has reduced utilization of certain of our oncology products by participating physician practices and expect it to continue to do so in the future. Additionally, in late 2019, CMS announced a request for information on the Oncology Care First model, a new voluntary model that builds on the Oncology Care Model. CMS recently finalized a rule that, starting January 1, 2023, unless a manufacturer can ensure that the full amount of manufacturer patient assistance programs is passed on to the patient, such amount will be treated as a price reduction that will be taken into account when reporting our Best Price and/or Average Manufacturer Price (AMP). Given the use by PBMs and insurers of copay accumulator adjustment programs to apply such patient assistance for the benefit of such companies and not to defray costs to patients, it could be difficult to impossible for manufacturers to ensure that the full value of such amounts is being passed on to the patient. This new policy, if implemented, would have significant implications for our ability to offer copay assistance programs.

In this dynamic environment, we are unable to predict which or how many federal policy, legislative, regulatory, executive or administrative changes may ultimately be, or effectively estimate the consequences to our business if, enacted and implemented. However, to the extent that these or other federal government initiatives further decrease or modify the coverage or reimbursement available for our products, require that we pay increased rebates or shift other costs to us, limit or affect our decisions regarding the pricing of or otherwise reduce the use of our U.S. products, or limit our ability to offer co-pay payment assistance to commercial patients, such actions could have a material adverse effect on our business and results of operations.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products. U.S. government price reporting regulations are complex and may require a biopharmaceutical manufacturer to update certain previously submitted data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which

could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data, we also may be required to pay additional rebates and provide additional discounts.

—Changing reimbursement and pricing actions in various states have negatively affected, and may continue to negatively affect, access to, and have affected, and may continue to affect, sales of our products

At the state level, government actions or ballot initiatives can also affect how our products are covered and reimbursed and/or create additional pressure on our pricing decisions. A number of states have adopted, and many other states are considering, drug importation programs or other new pricing actions, including proposals designed to require biopharmaceutical manufacturers publicly to report proprietary pricing information, limit price increases or place a maximum price ceiling or cap on biopharmaceutical products. Existing and proposed state pricing laws have added complexity to the pricing of drugs and may already be affecting industry pricing decisions. For example, a California law, the constitutionality of which is currently being challenged, purports to require biopharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. Similar laws exist in Oregon and Washington. States are also seeking to change the way they pay for drugs for patients covered by state programs. California adopted a 2020-21 budget that incorporates international pricing into Medicaid supplemental rebate negotiations and allows its Medicaid program to seek federal approval to extend supplemental rebates to non-Medicaid populations. New York, Massachusetts and Ohio have established Medicaid drug spending caps, and additional states may consider doing so as they face budget deficits from the effects of COVID-19. Additionally, Colorado, Florida, Maine, New Hampshire, New Mexico and Vermont have enacted laws, and several other states have proposed laws, to facilitate the importation of drugs from Canada. Other states could adopt similar approaches or could pursue different policy changes in a continuing effort to reduce their costs. Ultimately, as with U.S. federal government actions, existing or future state government actions or ballot initiatives may also have a material adverse effect on our product sales, business and results of operations.

—U.S. commercial payer actions have affected and may continue to affect access to and sales of our products

Payers, including healthcare insurers, PBMs, integrated healthcare delivery systems (vertically-integrated organizations built from the consolidation of healthcare insurers and PBMs) and group purchasing organizations, increasingly seek ways to reduce their costs. With increasing frequency, payers are adopting benefit plan changes that shift a greater proportion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient copay or coinsurance obligations and more significant limitations on patients' use of manufacturer commercial copay assistance programs. Further, government regulation of payers may affect these trends. For example, CMS recently finalized a policy that could cause commercial payers to adopt copay accumulator adjustment programs more widely. Payers have sought, and will likely continue to seek, price discounts or rebates in connection with the placement of our products on their formularies or those they manage, particularly in treatment areas where the payer has taken the position that multiple branded products are therapeutically comparable. Payers also control costs by imposing restrictions on access to or usage of our products, such as Step Therapy, or requiring that patients receive the payer's prior authorization before covering the product or that patients use a mail-order pharmacy or a limited network of payer fully-owned mail-order or specialty pharmacies. Payers may also choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. For example, some payers require physicians to demonstrate or document that the patients for whom Repatha® has been prescribed meet payer utilization management criteria, and these requirements have limited, and may continue to limit, patient access to Repatha® treatment. In an effort to reduce barriers to access, we reduced the net price of Repatha® by providing greater discounts and rebates to payers, including PBMs that administer Medicare Part D prescription drug plans. However, affordability of patient out-of-pocket co-pay cost has limited and may continue to limit patient use. For example, in late 2018 and early 2019, in response to a very high percentage of Medicare patients abandoning their Repatha® prescriptions rather than pay their co-pay payment, we introduced a set of new National Drug Codes to make Repatha® available at a lower list price to attempt to address affordability for patients, particularly those on Medicare and on December 31, 2019, we discontinued the higher list price option for Repatha®. Despite these net and list price reductions, some payers have restricted, and may continue to restrict, patient access and may change formulary coverage for Repatha®, seek further discounts or rebates or take other actions that could reduce our sales of Repatha®. These factors have limited, and may continue to limit, patient affordability and use, and negatively affect Repatha® sales.

Further, significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs, which places greater pressure on pricing and usage negotiations with biopharmaceutical manufacturers, significantly increasing discount and rebate requirements and limiting patient access and usage. For example, in the United States, in 2020, the top five integrated health plans and PBMs controlled about 85% of all pharmacy prescriptions. The consolidation among insurers, PBMs and other payers, including through integrated healthcare delivery systems and/or with specialty or mail-order pharmacies and pharmacy retailers, has increased the negotiating leverage such entities have over us and other biopharmaceutical manufacturers, and has resulted in greater price discounts, rebates and service fees realized by those payers. In 2019 and 2020, CVS and Express Scripts created Rebate Management Organizations that further increase their respective leverage to negotiate deeper discounts. Ultimately, additional discounts, rebates, fees, coverage or plan changes, restrictions or exclusions imposed by these commercial payers could have a material adverse effect on our product sales, business and results of operations. Policy reforms advanced by Congress or the Administration that refine the role of PBMs in the U.S. marketplace could have downstream implications or consequences for our business and how we interact with these entities.

—Government and commercial payer actions outside the United States have affected and will continue to affect access to and sales of our products

Outside the United States, we expect countries will also continue to take actions to reduce their drug expenditures. See Item 1. Business—Reimbursement. IRP has been widely used by many countries outside the United States to control costs based on an external benchmark of a product's price in other countries. IRP policies can change quickly and frequently and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. In addition, countries may refuse to reimburse or may restrict the reimbursed population for a product when their national health technology assessments do not consider a medicine to demonstrate sufficient clinical benefit beyond existing therapies or to meet certain cost effectiveness thresholds. For example, despite the EMA's approval of Repatha® for the treatment of patients with established atherosclerotic disease, the reimbursement for Repatha® in France is limited to a narrower patient population (such as those with homozygous familial hypercholesterolemia) following a national health technology assessment. While the pricing and reimbursement process in that country remains ongoing, the assessment currently limits our efforts in France to expand Repatha® access to the broader patient population covered by the approved label. Some countries decide on reimbursement between potentially competing products through national or regional tenders that often result in one product receiving most or all of the sales in that country or region. Failure to obtain coverage and reimbursement for our products, a deterioration in their existing coverage and reimbursement, or a decline in the timeliness or certainty of payment by payers to physicians and other providers has negatively affected, and may further negatively affect, the ability or willingness of healthcare providers to prescribe our products for their patients and otherwise negatively affect the use of our products or the prices we realize for them. Such changes have had, and could in the future have, a material adverse effect on our product sales, business and results of operations.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. Professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities. Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies. In addition, a growing number of organizations are providing assessments of the value and pricing of biopharmaceutical products, and even organizations whose guidelines have historically been focused on clinical matters have begun to incorporate analyses of the cost effectiveness of various treatments into their treatment guidelines and recommendations. Value assessments may come from private organizations that publish their findings and offer recommendations relating to the products' reimbursement by government and private payers. Some companies and payers have announced pricing and payment decisions based in part on the assessments of private organizations. In addition, government health technology assessment organizations in many countries make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service effects of new, emerging and existing medicines and treatments. Such health technology assessment organizations have recommended, and may in the future recommend, reimbursement for certain of our products for a narrower indication than was approved by applicable regulatory agencies or may recommend against reimbursement entirely. See *Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our*

profitability. Such recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could have a material adverse effect on our product sales, business and results of operations. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price of our common stock.

The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability.

We are subject to income and other taxes in the United States and other jurisdictions in which we do business. As a result, our provision for income taxes is derived from a combination of applicable tax rates in the various places we operate. Significant judgment is required for determining our provision for income tax.

Our tax returns are routinely examined by tax authorities in the United States and other jurisdictions in which we do business, and a number of audits are currently underway. Tax authorities, including the Internal Revenue Service (IRS), are becoming more aggressive in their audits and are particularly focused on the allocations of income and expense among tax jurisdictions. In 2017, we received a Revenue Agent Report (RAR) and a modified RAR from the IRS for the years 2010, 2011 and 2012 proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. However, we have been unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a Notice of Deficiency which we would expect to vigorously contest through the judicial process. In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagree with the 2013, 2014 and 2015 proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. The IRS audit for years 2016, 2017 and 2018 is expected to start in the near term. We are also currently under examination by a number of other state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse effect on the results of our operations.

Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities and changes in applicable tax laws, regulations or administrative interpretations thereof. The Tax Cuts and Jobs Act (the 2017 Tax Act) is complex and a large volume of regulations and guidance has been issued and could be subject to different interpretations. We could face audit challenges to our application of the 2017 Tax Act. The new Administration and Congress could make changes to existing tax law, including an increase in the corporate tax rate and the tax rate on foreign earnings. Changes to existing tax law in the U.S., the U.S. territory of Puerto Rico, or other jurisdictions, including efforts by the OECD to align countries on corporate tax matters that would likely result in tax increases where we do business could have a material adverse effect on the results of our operations.

Our business may be affected by litigation and government investigations.

We and certain of our subsidiaries are involved in legal proceedings. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. Civil and criminal litigation is inherently unpredictable, and the outcome can result in costly verdicts, fines and penalties, exclusion from federal healthcare programs and/or injunctive relief that affect how we operate our business. Defense of litigation claims can be expensive, time consuming and distracting, and it is possible that we could incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our product sales, business and results of operations. In addition, product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention and could adversely affect our reputation and the demand for our products. We and certain of our subsidiaries have previously been named as defendants in product liability actions for certain of our products.

We are also involved in government investigations that arise in the ordinary course of our business. In recent years, there has been a trend of increasing government investigations and litigations against companies operating in our industry, both in the United States and around the world. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability.* Our business activities outside of the United States are subject to the FCPA and similar antibribery or anticorruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. We cannot ensure that all our employees, agents, contractors, vendors, licensees, partners or collaborators will comply with all applicable laws and regulations. On April 25, 2019, we entered into a settlement agreement with the DOJ and the OIG of the HHS to settle certain allegations relating to our support of independent charitable organizations that provide patients with financial assistance to access their medicines. As a result, we entered into a corporate integrity agreement with the OIG that requires us to maintain a corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years. While we expect to fully comply with all of our obligations under the corporate integrity agreement, failure to do so could result in substantial penalties and potential exclusion from government healthcare programs. We may also see new government investigations of or actions against us citing novel theories of recovery. For example, prosecutors are placing greater scrutiny on patient support programs, including commercial copay assistance programs, and further enforcement actions and investigations regarding such programs could limit our ability to provide co-pay assistance to commercial patients. Greater scrutiny has also been placed on sponsorships, speaker programs and other arrangements where healthcare professionals receive remuneration, travel or other value to participate in certain events, and further enforcement actions could limit our ability to participate in such arrangements. Any of these results could have a material adverse effect on our business and results of operations.

RISKS RELATED TO COMPETITION

Our products face substantial competition and our product candidates are also likely to face substantial competition.

We operate in a highly competitive environment. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We expect that our products and product candidates will compete with existing drugs, new drugs currently in development, drugs currently approved for other indications that may later be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. Large pharmaceutical companies and generics manufacturers of pharmaceutical products are expanding into the biotechnology field, and some pharmaceutical companies and generics manufacturers have formed partnerships to pursue biosimilars. With the proliferation of companies pursuing biopharmaceuticals, a number of our product candidates may enter markets with one or more competitors or with competitors soon to arrive. In addition, some of our competitors may have technical, competitive or other advantages over us for the development of technologies and processes or greater experience in particular therapeutic areas, and consolidation among pharmaceutical and biotechnology companies can enhance such advantages. These advantages may make it difficult for us to compete with them successfully to discover, develop and market new products and for our current products to compete with new products or new product indications they may bring to market. As a result, our products have been competing and may continue to compete, and our product candidates may compete, against products or product candidates that offer higher rebates or discounts, lower prices, equivalent or superior efficacy, better safety profiles, easier administration, earlier market availability or other competitive features. If we are unable to compete effectively, this could reduce sales, which could have a material adverse effect on our business and results of operations.

Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. Driven by cost pressures, efforts to limit or weaken patent protection for our industry are increasing. For example, the COVID-19 pandemic has resulted in increased interest in compulsory licenses, march-in rights or other governmental interventions, both in the United States and internationally, related to the procurement of drugs. See *The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations.* Third parties have challenged and may continue to challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. Challenges to patents may come from potential competitors or from parties other than those who seek to market a potentially-infringing product. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We have been in the past, are currently and expect to be in the future, involved in patent litigation. These matters have included, and may in the future include, litigation with manufacturers of products that purport to be biosimilars of certain of our products for patent infringement and for failure to comply with certain provisions of the Biologics Price Competition and Innovation Act of 2009 (BPCIA). A determination made by a court, agency or tribunal concerning infringement, validity, enforceability, injunctive or economic remedy, or the right to patent protection, for example, are typically subject to appellate or administrative review. Upon review, such initial determinations may be afforded little or no deference by the reviewing tribunal and may be affirmed, reversed or made the subject of reconsideration through further proceedings. A patent dispute or litigation has not discouraged, and may not in the future discourage, a potential violator from bringing the allegedly-infringing product to market prior to a final resolution of the dispute or litigation. The period from inception until resolution of a patent dispute or litigation is subject to the availability and schedule of the court, agency or tribunal before which the dispute or litigation is pending. We have been, and may in the future be, subject to competition during this period and may not be able to recover fully from the losses, damages and harms we incur from infringement by the competitor product even if we prevail. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities, be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Further, under the Hatch-Waxman Act, our products approved by the FDA under the FDCA have been, and may in the future be, the subject of patent litigation with generics competitors before expiry of the five-year period of data exclusivity provided for under the Hatch-Waxman Act and prior to the expiration of the patents listed for the product. Likewise, our innovative biologic products have been, and may in the future be, the subject of patent litigation prior to the expiration of our patents and, with respect to competitors seeking approval as a biosimilar or interchangeable version of our products, prior to the 12-year exclusivity period provided under the BPCIA. In addition, we may face patent litigation involving claims that the biosimilar product candidates we are working to develop infringe the patents of other companies, including those that manufacture, market or sell the applicable reference products or who are developing or have developed other biosimilar versions of such products. Due to the COVID-19 pandemic, there may be delays in ongoing or new patent office or court proceedings in the U.S. or abroad that may delay the outcome of such proceedings. While we have attempted, and expect to continue to attempt, to challenge the patents held by other companies, our efforts may be unsuccessful. Alternatively, such patents have contributed, and may in the future contribute, to a decision by us to not pursue all of the same labeled indications as are held by these companies. For examples of and information related to our patent litigation, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Certain of the existing patents on our products have expired. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents. As our patents expire, competitors are able to legally produce and market similar products or technologies, including biosimilars, which has had, and may continue to have, a material adverse

effect on our product sales, business and results of operations. In addition, competitors have been, and may continue to be, able to invalidate, design around or otherwise circumvent our patents and sell competing products.

We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.

We currently face competition from biosimilars and generics in most of the territories in which we operate, including Europe and the United States, and we expect to face increasing biosimilar and/or generics competition this year and beyond. Expiration or successful challenge of applicable patent rights or expiration of an applicable exclusivity period has accelerated such competition, and we expect to face more litigation regarding the validity and/or scope of our patents. Our products have also experienced greater competition from lower cost biosimilars or generics that come to market when branded products that compete with our products lose their own patent protection. To the extent that governments adopt more permissive regulatory approval standards and competitors are able to obtain broader or expedited marketing approval for biosimilars and generics, the rate of increased competition for our products could accelerate.

In the EU, biosimilars are evaluated for marketing authorization pursuant to a set of general and product class-specific guidelines. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU countries and some Canadian provinces have adopted or are considering the adoption of biosimilar uptake measures such as physician prescribing quotas or automatic pharmacy substitution of biosimilars for the corresponding reference products. Some EU countries impose automatic price reductions upon market entry of one or more biosimilar competitors. While the degree of competitive effects of biosimilar competition differs between EU countries and between products, in the EU the overall use of biosimilars and the rate at which product sales of innovative products are being affected by biosimilar competition is increasing.

In the United States, the BPCIA authorizes the FDA to approve biosimilars via a separate, abbreviated pathway. See Item 1. Business—Government Regulation—Regulation in the United States—Approval of Biosimilars. The first biosimilar entrant into the U.S. market was Sandoz's Zarxio® (filgrastim-sndz), a biosimilar version of NEUPOGEN®, in 2015. Since then, the FDA has approved additional biosimilars, including biosimilar versions of Neulasta®, EPOGEN® and ENBREL, and a growing number of companies have announced that they are also developing biosimilar versions of our products. Four biosimilar versions of Neulasta® are now marketed in the United States, and we expect other biosimilar versions of Neulasta® to receive approval in 2021 and beyond. Impact to our Neulasta® sales has accelerated as additional competitors have launched. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. An approved biosimilar version of EPOGEN® has also launched in the United States, and we are currently involved in patent litigations with the manufacturers of the approved biosimilar versions of ENBREL. Manufacturers of biosimilars have attempted, and may in the future attempt, to compete with our products by offering lower list prices, greater discounts or rebates, or contracts that offer longer-term pricing or a broader portfolio of other products. Companies pursuing development of biosimilar versions of our products have challenged and may continue to challenge our patents well in advance of the expiration of our material patents. For example, we recently successfully defended our ENBREL patents against a litigation challenge. For examples of and information related to our biosimilars and generics patent litigation, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. See *Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.*

The U.S. pathway includes the option for biosimilar products that meet certain criteria to be approved as interchangeable with their reference products. Some companies currently developing or already marketing biosimilars may seek to obtain interchangeable status from the FDA, which could potentially allow pharmacists to substitute those biosimilars for our reference products without prior approval from the prescriber in most states. In November 2019, the FDA issued draft guidance that provides that comparative immunogenicity studies will not generally be expected for biosimilar and interchangeable insulin products. This may open the door for other product-specific guidance development and the removal of the expectation for certain studies, which may contribute to increased biosimilar competition for our innovative products.

In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law's provisions regarding which new products receive data exclusivity. In late 2019, the previous Administration agreed to remove from the United States-Mexico-Canada Agreement a requirement for at least 10 years of data exclusivity for biologic products. Also, the FDA is considering whether subsequent changes to a licensed biologic would be protected by the remainder of the reference product's original 12-year exclusivity period (a concept known in the generic drug context as "umbrella exclusivity"). If the FDA were to decide that umbrella exclusivity does not apply to biological reference

products or were to make other changes to the exclusivity period, this could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, legislative and regulatory efforts to promote competition through policies enabling easier generic and biosimilar approval and commercialization, including efforts to lower standards for demonstrating biosimilarity or interchangeability, limit patents that may be litigated and/or patent settlements, implement preferential reimbursement policies for biosimilars and passage of new laws requiring more disclosure in the FDA's Orange and Purple Books.

Upon the expiration or loss of patent protection and/or applicable exclusivity for one of our small molecule products, we can lose the majority of revenues for that product in a very short period of time. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. Additionally, if one of our small molecule products is the subject of an FDA Written Request for pediatric studies and we are unable to adequately complete these studies, we may not obtain the pediatric exclusivity award that extends existing patents for the product by an additional six months. For example, as a result of the product already introduced and/or that could further be introduced into the U.S. market, our product sales for Sensipar® have been adversely affected and could be further materially and adversely affected by competing generics.

California is the first state to have passed legislation, effective on January 1, 2020, against "pay for delay" settlements of patent infringement claims filed by manufacturers of generics or biosimilars where anything of value is given in exchange for settlement. Under this law, such settlement agreements are presumptively anticompetitive. The law may result in prolonged litigation and fewer settlements. Other states, including Connecticut, New York, Illinois, and Minnesota, may adopt similar laws or a similar law could be adopted at the federal level.

While we are unable to predict the precise effects of biosimilars and generics on our products, we are currently facing and expect to face greater competition in the United States, Europe and elsewhere in 2021 and beyond as a result of biosimilar and generic competition and, in turn, downward pressure on our product prices and sales. This competition has had and could increasingly have a material adverse effect on our product sales, business and results of operations.

Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively affect our business.

Certain of our distributors, customers and payers have substantial purchasing leverage, due to the volume of our products they purchase or the number of patient lives for which they provide coverage. The substantial majority of our U.S. product sales is made to three pharmaceutical product wholesaler distributors: AmerisourceBergen, McKesson and Cardinal Health. These distributors, in turn, sell our products to their customers, which include physicians or their clinics, dialysis centers, hospitals and pharmacies. One of our products, EPOGEN®, is sold primarily to free-standing dialysis clinics. DaVita owns or manages a large number of the outpatient dialysis facilities located in the United States and accounts for approximately 90% of all EPOGEN® sales. Similarly, as discussed above, there has been significant consolidation in the health insurance industry, including that a small number of PBMs now oversee a substantial percentage of total covered lives in the United States. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability*. The three largest PBMs in the United States are now part of major health insurance providers. The growing concentration of purchasing and negotiating power by these entities may put pressure on our pricing due to their ability to extract price discounts on our products, fees for other services or rebates, negatively affecting our bargaining position, sales and/or profit margins. In addition, decisions by these entities to purchase or cover less or none of our products in favor of competitive products could have a material adverse effect on our product sales, business and results of operations due to their purchasing volume. Further, if one of our significant wholesale distributors encounters financial or other difficulties and becomes unable or unwilling to pay us all amounts that such distributor owes us on a timely basis, or at all, it could negatively affect our business and results of operations. In addition, if one of our significant wholesale distributors becomes insolvent or otherwise unable to continue its commercial relationship with us in its present form, it could significantly disrupt our business and adversely affect our product sales, our business and results of operations unless suitable alternatives are timely found or lost sales are absorbed by another distributor.

RISKS RELATED TO RESEARCH AND DEVELOPMENT

We may not be able to develop commercial products despite significant investments in R&D.

Amgen invests heavily in R&D. Successful product development in the biotechnology industry is highly uncertain, and very few R&D projects produce commercial products. Product candidates, including biosimilar product candidates, or new indications for existing products (collectively, product candidates) that appear promising in the early phases of development may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it achieved its primary endpoints and/or demonstrated positive preclinical or early clinical trial results, for reasons that could include changes in the standard of care of medicine or expectations of health authorities;

- the product candidate was not effective or not more effective than currently available therapies in treating a specified condition or illness;
- the product candidate was not cost effective in light of existing therapeutics;
- the product candidate had harmful side effects in animals or humans;

- the necessary regulatory bodies, such as the FDA or EMA, did not approve the product candidate for an intended use;
- the product candidate was not economical for us to manufacture and commercialize;
- other parties had or may have had proprietary rights relating to our product candidate, such as patent rights, and did not let us sell it on reasonable terms, or at all;
- we and certain of our licensees, partners, contracted organizations or independent investigators may have failed to effectively conduct clinical development or clinical manufacturing activities;
- the pathway to regulatory approval or reimbursement for product candidates was uncertain or not well-defined;
- the biosimilar product candidate failed to demonstrate the requisite biosimilarity to the applicable reference product, or was otherwise determined by a regulatory authority to not meet applicable standards for approval; and
- a companion diagnostic device that is required with the use of a product candidate is not approved by the necessary regulatory authority.

We have spent considerable time, energy and resources developing our expertise in human genetics and acquiring access to libraries of genetic information with the belief that genetics could meaningfully aid our search for new medicines and help guide our R&D decisions and investments. We have focused our R&D strategy on drug targets validated by genetic or other compelling human evidence. However, product candidates based on genetically validated targets remain subject to the uncertainties of the drug development process and may not reach the market for a number of reasons, including the factors listed above.

A number of our product candidates have failed or been discontinued at various stages in the product development process. For example, in 2015, we terminated our participation in the co-development and commercialization of brodalumab, a product candidate that was in phase 3, with AstraZeneca. The decision was based on events of suicidal ideation and behavior in the brodalumab program that occurred late in the development program, which we believed likely would necessitate restrictive labeling that would limit the appropriate patient population. Inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product for any of the reasons discussed could potentially have a negative effect on our product sales and earnings and could result in a significant impairment of in-process research and development (IPR&D) or other intangible assets.

We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.

Before we sell any products, we must conduct clinical trials to demonstrate that our product candidates are safe and effective for use in humans. The results of those clinical trials are used as the basis to obtain approval from regulatory authorities such as the FDA and EMA. See *Our current products and products in development cannot be sold without regulatory approval*. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims. The length of time, number of trial sites and number of patients required for clinical trials vary substantially, and we may spend several years and incur substantial expense in completing certain clinical trials. In addition, we may have difficulty finding a sufficient number of clinical trial sites and patients to participate in our clinical trials, particularly if competitors are conducting clinical trials in similar patient populations. See *The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations.* Patients may withdraw from clinical trials at any time, and privacy laws and/or other restrictions in certain countries may restrict the ability of clinical trial investigators to conduct further follow-up on such patients, which may adversely affect the interpretation of study results. Delays and complications in planned clinical trials can result in increased development costs, associated delays in regulatory approvals and in product candidates reaching the market and revisions to existing product labels.

Further, to increase the number of patients available for enrollment in our clinical trials, we have opened, and will continue to open, clinical sites and enroll patients in a number of locations where our experience conducting clinical trials is more limited, including Russia, India, China, South Korea, the Philippines, Singapore and some Central and South American countries, either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to understand the unique regulatory environments of individual countries. For other examples of the risks of conducting clinical trials in China, see also *Our sales and operations are subject to the risks of doing business internationally, including in emerging markets*. Further, we must ensure the timely production, distribution and delivery of the clinical supply of our product candidates to numerous and varied clinical trial sites. Additionally, regional disruptions, including natural and man-made disasters or health emergencies (such as novel viruses or pandemics such as the one we are currently experiencing with COVID-19), could significantly disrupt the timing of clinical trials. If we fail to adequately manage the design, execution and diverse regulatory aspects of our large and/or complex clinical trials or to manage the production or distribution of our clinical supply, or such sites experience disruptions as a result of a natural/man-made disaster or health emergency, corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates or could lose our ability to market existing products in certain therapeutic areas or altogether. For example, our clinical trials have been adversely affected by the COVID-19 pandemic. See *The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations.* If we are unable to market and sell our products or product candidates or to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations could be materially and adversely affected.

We rely on independent third-party clinical investigators to recruit patients and conduct clinical trials on our behalf in accordance with applicable study protocols, laws and regulations. Further, we rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations. In some circumstances, we enter into co-development arrangements with other pharmaceutical and medical devices companies that provide for the other company to conduct certain clinical trials for the product we are co-developing or to develop a diagnostic test used in screening or monitoring patients in our clinical trials. See *Some of our pharmaceutical pipeline and of our commercial product sales rely on collaborations with third parties, which may adversely affect the development and sale of our products.* We also may acquire companies that have past or ongoing clinical trials or rights to products or product candidates for which clinical trials have been or are being conducted. These trials may not have been conducted to the same standards as ours; however, once an acquisition has been completed we assume responsibility for the conduct of these trials, including any potential risks and liabilities associated with the past and prospective conduct of those trials. If regulatory authorities determine that we or others, including our licensees or co-development partners, or the independent investigators or vendors selected by us, our co-development partners or by a company we have acquired or from which we have acquired rights to a product or product candidate, have not complied with regulations applicable to the clinical trials, those authorities may refuse or reject some or all of the clinical trial data or take other actions that could delay or otherwise negatively affect our ability to obtain or maintain marketing approval of the product or indication. In addition, delays or failures to develop diagnostic tests for our clinical trials can affect the timely enrollment of such trials and lead to delays or inability to obtain marketing approval. If we were unable to market and sell our products or product candidates, our business and results of operations could be materially and adversely affected.

In addition, some of our clinical trials utilize drugs manufactured and marketed by other pharmaceutical companies. These drugs may be administered in clinical trials in combination with one of our products or product candidates or in a head-to-head study comparing the products' or product candidates' relative efficacy and safety. In the event that any of these vendors or pharmaceutical companies have unforeseen issues that negatively affect the quality of their work product or create a shortage of supply, or if we are otherwise unable to obtain an adequate supply of these other drugs, our ability to complete our applicable clinical trials and/or evaluate clinical results may also be negatively affected. As a result, such quality or supply problems could adversely affect our ability to timely file for, gain or maintain regulatory approvals worldwide.

Clinical trials must generally be designed based on the current standard of medical care. However, in certain diseases, such as cancer, the standard of care is evolving rapidly. In some cases, we may design a clinical trial based on the standard of care we anticipate will exist at the time our study is completed. The duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on standards of medical care that are no longer or that have not become the current standards by the time such trials are completed, limiting

the utility and application of such trials. Additionally, the views of regulatory agencies relating to the requirements for accelerated approval may change over time, and trial designs that were sufficient to support accelerated approvals for some oncology products may not be considered sufficient for later candidates. We may not obtain favorable clinical trial results and therefore may not be able to obtain regulatory approval for new product candidates or new indications for existing products and/or maintain our current product labels. Participants in clinical trials of our products and product candidates may also suffer adverse medical events or side effects that could, among other factors, delay or terminate clinical trial programs and/or require additional or longer trials to gain approval.

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a risk management plan for our product or for approval of a new indication. For example, in connection with the June 2011 ESA label changes, we agreed to and conducted additional clinical trials examining the use of ESAs in CKD. Additional clinical trials we initiate, including those required by the FDA, could result in substantial additional expense, and the outcomes could result in further label restrictions or the loss of regulatory approval for an approved indication, each of which could have a material adverse effect on our product sales, business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our products, our business and results of operations.

Our current products and products in development cannot be sold without regulatory approval.

Our business is subject to extensive regulation by numerous state and federal government authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in foreign countries to obtain approval from regulatory authorities before we manufacture, market and sell our products. Once our products are approved, the FDA and other U.S. and foreign regulatory agencies have substantial authority to require additional testing and reporting, perform inspections, change product labeling or mandate withdrawals of our products. Failure to comply with applicable regulatory requirements may subject us to administrative and/or judicially imposed sanctions or monetary penalties as well as reputational and other harms. The sanctions could include the FDA's or foreign regulatory authorities' refusals to approve pending applications, delays in obtaining or withdrawals of approvals, delays or suspensions of clinical trials, warning letters, product recalls or seizures, total or partial suspensions of our operations, injunctions, fines, civil penalties and/or criminal prosecutions.

Obtaining and maintaining regulatory approvals have been, and will continue to be, increasingly difficult, time-consuming and costly. Legislative bodies or regulatory agencies could enact new laws or regulations, change existing laws or regulations or change their interpretations of laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products or product candidates. The rate and degree of change in existing laws and regulations and regulatory expectations have accelerated in established markets, and regulatory expectations continue to evolve in emerging markets. We are unable to predict whether and when any further changes to laws or regulatory policies affecting our business could occur, such as changes to laws or regulations governing manufacturer communications concerning drug products and drug product candidates and whether such changes could have a material adverse effect on our product sales, business and results of operations. In the United States, a partial federal government shutdown halted the work of many federal agencies and their employees from late December 2018 through late January 2019. A subsequent extended shutdown could result in reductions or delays of FDA's activities, including with respect to our ongoing clinical programs, our manufacturing of our products and product candidates and our product approvals.

Regulatory authorities have questioned, and may in the future question, the sufficiency for approval of the endpoints we select for our clinical trials. A number of our products and product candidates have been evaluated in clinical trials using surrogate endpoints that measure an effect that is known to correlate with an ultimate clinical benefit. For example, a therapeutic oncology product candidate may be evaluated for its ability to reduce or eliminate minimal residual disease (MRD), or to extend the length of time during and after the treatment that a patient lives without the disease worsening, measured by PFS. Demonstrating that the product candidate induces MRD-negative responses or produces a statistically significant improvement in PFS does not necessarily mean that the product candidate will show a statistically significant improvement in overall survival or the time that the patients remain alive. In the CV setting, a heart disease therapeutic candidate may be evaluated for its ability to reduce LDL-C levels, as an elevated LDL-C level has been a surrogate endpoint for CV events such as death, heart attack and stroke. The use of surrogate endpoints such as PFS and LDL-C reduction, in the absence of other measures of clinical benefit, may not be sufficient for broad usage or approval even when such results are statistically significant. Regulatory authorities could also add new requirements, such as the completion of enrollment in a confirmatory study or the completion of an outcomes study or a meaningful portion of an outcomes study, as conditions for obtaining approval or obtaining an indication. For example, despite demonstrating that Repatha® reduced LDL-C levels in a broad patient population, only after our large phase 3 outcomes study evaluating the ability of Repatha® to prevent CV events met certain of its primary composite endpoint and key secondary composite endpoint did the FDA grant a broader approval of Repatha® to reduce the risk of certain CV events, and also to be used, alone or in combination with other lipid-lowering therapies, for the treatment of adults with primary hyperlipidemia to reduce LDL-C. There may also be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to other existing treatment options can be shown. The imposition of additional requirements or our inability to meet them in a timely fashion, or at all, has delayed, and may in the future

delay, our clinical development and regulatory filing efforts, delay or prevent us from obtaining regulatory approval for new product candidates or new indications for existing products, or prevent us from maintaining our current product labels.

Some of our products have been approved by U.S. and foreign regulatory authorities on an accelerated or conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, in March 2018, we announced that the FDA approved BLINCYTO® under accelerated approval for the treatment of adults and children with B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with MRD greater than or equal to 0.1 percent. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Regulatory authorities are placing greater focus on monitoring products originally approved on an accelerated or conditional basis and on whether the sponsors of such products have met the conditions of the accelerated or conditional approvals. If we are unable to fulfill the regulators' requirements that were conditions of a product's accelerated or conditional approval and/or if regulators reevaluate the data or risk-benefit profile of our product, the conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change the product's labeled indications or even withdraw the product from the market.

Regulatory authorities can also impose post-marketing pediatric study requirements. Failure to fulfill such requirements may result in regulatory or enforcement action, including financial penalties or the invalidation of a product's marketing authorization.

Safety problems or signals can arise as our products and product candidates are evaluated in clinical trials, including investigator sponsored studies, or as our marketed products are used in clinical practice. We are required continuously to collect and assess adverse events reported to us and to communicate to regulatory agencies these adverse events and safety signals regarding our products. Regulatory agencies periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. In the United States, for our products with approved REMS (see Item 1. Business—Government Regulation—Postapproval Phase), we are required to submit periodic assessment reports to the FDA to demonstrate that the goals of the REMS are being met. REMS and other risk management programs are designed to ensure that a drug's benefits outweigh the risks and vary in the elements they contain. If the FDA is not satisfied with the results of the periodic assessment reports we submit for any of our REMS, the FDA may also modify our REMS or take other regulatory actions, such as implementing revised or restrictive labeling. The drug delivery devices approved for use in combination with our products are also subject to regulatory oversight and review for safety and malfunctions. See *Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.* If regulatory agencies determine that we or other parties (including our clinical trial investigators, those operating our patient support programs or licensees of our products) have not complied with the applicable reporting, other pharmacovigilance or other safety or quality assessment requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including fines, marketing authorization withdrawal and other penalties. Our product candidates and marketed products can also be affected by safety problems or signals occurring with respect to products that are similar to ours or that implicate an entire class of products. Further, as a result of clinical trials, including sub-analyses or meta-analyses of earlier clinical trials (a meta-analysis involves the use of various statistical methods to combine results from previous separate but related studies) performed by us or others, concerns may arise about the sufficiency of the data or studies underlying a product's approved label. Such actual or perceived safety problems or concerns can lead to:

- revised or restrictive labeling for our products, or the potential for restrictive labeling that has resulted, and may in the future result, in our decision not to commercialize a product candidate;
- requirement of risk management or minimization activities or other regulatory agency compliance actions related to the promotion and sale of our products;
- post-marketing commitments, mandated post-marketing requirements or pharmacovigilance programs for our approved products;
- product recalls of our approved products;
- required changes to the processes used in the manufacture of our products, which could increase our manufacturing costs and affect the availability of contract manufacturers we may utilize to assist in such manufacturing;
- revocation of approval for our products from the market completely, or within particular therapeutic areas or patient types;
- increased timelines or delays in being approved by the FDA or other regulatory bodies; and/or

- treatments or product candidates not being approved by regulatory bodies.

For example, after an imbalance in positively adjudicated CV serious adverse events was observed in one of the phase 3 clinical trials for EVENITY® but not in another, larger phase 3 study, in April 2019 the FDA approved EVENITY® for the treatment of osteoporosis in postmenopausal women at high risk for fracture, along with a post-marketing requirement. The requirement includes a five-year observational feasibility study that could be followed by a comparative safety study or trial.

In addition to our innovative products, we are working to develop and commercialize biosimilar versions of a number of products currently manufactured, marketed and sold by other pharmaceutical companies. In some markets, there is not yet a legislative or regulatory pathway for the approval of biosimilars. In the United States, the BPCIA provided for such a pathway; while the FDA continues to implement it, discussions continue as to the evidence needed to demonstrate biosimilarity or interchangeability for specific products. See *We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.* Delays or uncertainties in the development or implementation of such pathways could result in delays or difficulties in getting our biosimilar products approved by regulatory authorities, subject us to unanticipated development costs or otherwise reduce the value of the investments we have made in the biosimilars area. Further, we cannot predict whether any repeal or reform of the ACA or other legislation or policy initiatives would affect the biosimilar pathway or have a material adverse effect on our development of biosimilars or on our marketed biosimilars. In addition, if we are unable to bring our biosimilar products to market on a timely basis and secure "first-to-market" or other advantageous positions, our future biosimilar sales, business and results of operations could be materially and adversely affected.

Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.

Many of our products and product candidates may be used in combination with a drug delivery device, such as an injector or other delivery system. For example, Neulasta® is available as part of the Neulasta® Onpro® kit, and our AutoTouch® reusable autoinjector is used with ENBREL Mini® single-dose prefilled cartridges. In addition, some of our products or product candidates, including many of our oncology product candidates, including sotorasib, may also require the use of a companion or other diagnostic device such as a device that determines whether the patient is eligible to use our drug or that helps ensure its safe and effective use. In some regions, including the United States, regulatory authorities may require contemporaneous approval of the companion diagnostic device and the therapeutic product; in others the regulatory authorities may require a separate study of the companion diagnostic device. Our product candidates or expanded indications of our products used with such devices may not be approved or may be substantially delayed in receiving regulatory approval if development or approval of such devices is delayed, such devices do not also gain or maintain regulatory approval or clearance, or if such devices do not remain commercially available. When approval of the product and device is sought under a single marketing drug application, the increased complexity of the review process may delay receipt of regulatory approval. In addition, some of these devices may be provided by single-source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies to supply and/or market the devices and, in some cases, to conduct the studies required for approval or clearance by the applicable regulatory agencies. We are also dependent on those third-party companies continuing to meet applicable regulatory or other requirements. Failure to successfully develop, modify, or supply the devices, delays in or failures of the Amgen or third-party studies, or failure of us or the third-party companies to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs; delays in, or failure to obtain or maintain, regulatory approval; and/or associated delays in a product candidate reaching the market or in the addition of new indications for existing products. We are also required to collect and assess user complaints, adverse events and malfunctions regarding our devices, and actual or perceived safety problems or concerns with a device used with our product can lead to regulatory actions and adverse effects on our products. See *Our current products and products in development cannot be sold without regulatory approval*. Additionally, regulatory agencies conduct routine monitoring and inspections to identify and evaluate potential issues with our devices. For example, in 2017, the FDA reported on its adverse event reporting system that it was evaluating our Neulasta® Onpro® kit. Subsequently, we implemented device and labeling enhancements to address product complaints received on this device. We continuously monitor complaints and adverse events and implement additional enhancements as needed. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop, supply, or gain or maintain approval for these devices could adversely affect sales of the related approved products.

Some of our pharmaceutical pipeline and our commercial product sales rely on collaborations with third parties, which may adversely affect the development and sale of our products.

We depend on alliances with other companies, including pharmaceutical and biotechnology companies, vendors and service providers, for the development of a portion of the products in our pharmaceutical pipeline and for the commercialization and sales of certain of our commercial products. For example, we have collaborations with third parties under which we share development rights, obligations and costs and/or commercial rights and obligations. See Item 1. Business—Business Relationships.

Failures by these parties to meet their contractual, regulatory, or other obligations to us or any disruption in the relationships between us and these third parties, could have a material adverse effect on our pharmaceutical pipeline and business. In addition, our collaborative relationships for R&D and/or commercialization and sales often extend for many years and have given, and may in the future give, rise to disputes regarding the relative rights, obligations and revenues of us and our collaboration partners, including the ownership or prosecution of intellectual property and associated rights and obligations. This could result in the loss of intellectual property rights or protection, delay the development and sale of potential pharmaceutical products, affect the effective sale and delivery of our commercialized products and lead to lengthy and expensive litigation, administrative proceedings or arbitration. For example, we are currently involved in litigation with Novartis over our collaboration agreements for the development and commercialization of Aimovig®. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. While our collaboration remains in place until the litigation is resolved and we remain committed to continuing to work with Novartis to sell and deliver Aimovig®, it is possible that the dispute may nevertheless affect the efficiency of operation and future growth of the collaboration. The litigation may also affect or delay, or lead to a termination of, other projects with Novartis.

Our efforts to collaborate with or acquire other companies, products, or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.

We seek innovation through significant investment in both internal R&D and external transactions, including collaborations, partnering, alliances, licenses, joint ventures, mergers and acquisitions (collectively, acquisition activity). Acquisition activities may be subject to regulatory approvals or other requirements that are not within our control. There can be no assurance that such regulatory or other approvals will be obtained or that all closing conditions required in connection with our acquisition activities will be satisfied or waived, which could result in us being unable to complete the planned acquisition activities.

Acquisition activities are complex, time consuming and expensive and may result in unanticipated costs, delays or other operational or financial problems related to integrating the acquired company and business with our company, which may divert our management's attention from other business issues and opportunities and restrict the full realization of the anticipated benefits of such transactions within the expected timeframe or at all. We may pay substantial amounts of cash, incur debt or issue equity securities to pay for acquisition activities, which could adversely affect our liquidity or result in dilution to our stockholders, respectively. Further, failures or difficulties in integrating or retaining new personnel or in integrating the operations of the businesses, products or assets we acquire (including related technology, commercial operations, compliance programs, manufacturing, distribution and general business operations and procedures) may affect our ability to realize the benefits of the transaction and grow our business and may result in us incurring asset impairment or restructuring charges. These and other challenges may arise in connection with our recent acquisition of Otezla® and/or collaboration with BeiGene, or with other acquisition activities, which could have a material adverse effect on our business, results of operations and stock price.

RISKS RELATED TO OPERATIONS

We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.

The global supply of our products and product candidates for commercial sales and for use in our clinical trials is significantly dependent on the uninterrupted and efficient operation of our manufacturing facilities, in particular

those in the U.S. territory of Puerto Rico and Thousand Oaks, California. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

We currently perform a substantial majority of our clinical manufacturing that supports our product candidates at our facility in Thousand Oaks, California. A substantial disruption in our ability to operate our Thousand Oaks manufacturing facility could materially and adversely affect our ability to supply our product candidates for use in our clinical trials, leading to delays in development of our product candidates.

In addition, we currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico. In recent years, Puerto Rico has been affected by natural disasters, including droughts in mid-2020, earthquakes in early 2020 and Hurricane Maria in 2017. These natural disasters have affected, and may continue to affect, public and private properties and Puerto Rico's electric grid and communications networks in the future. While the critical manufacturing areas of our commercial manufacturing facility were not significantly affected by these natural disasters, the restoration of electrical service on the island after Hurricane Maria was a slow process, and our facility operated with electrical power from backup diesel powered generators for some time. We also operated on backup generators for a few weeks after the early 2020 earthquakes in Puerto Rico. Further instability of the electric grid could require us to increase the use of our generators or to continue using them exclusively. In addition, future storms, earthquakes or other natural disasters or events could cause a more significant effect on our manufacturing operations. Puerto Rico and the rest of the world are facing the effects of the COVID-19 pandemic and the associated health and economic implications. Since March2020, the Governor of Puerto Rico issued Executive Orders requiring the lockdown of businesses and government facilities, imposing restrictions on business operations and a curfew on residents. Our operations and employees have been exempted from the lockdown and curfew, but we cannot predict how long these orders will continue in effect and what impact these orders and the COVID-19 pandemic will have on our future operations, and whether the Governor will issue future Executive Orders imposing stricter lockdown and curfew measures should COVID-19 cases rise in Puerto Rico. Although our ability to manufacture and supply our products has not, to date, been significantly affected by these natural disasters or the COVID-19 pandemic, a combination of these challenges or other issues that could give rise to any substantial disruption to our ability to operate our Puerto Rico manufacturing facility or get supplies and manufactured products transported to and from that location could materially and adversely affect our ability to supply our products and affect our product sales. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

Hurricane Maria, the earthquakes of early 2020 and the COVID-19 pandemic have placed greater stress on the island's already challenged economy. Beginning in 2016, the government of Puerto Rico defaulted on its roughly $72 billion in debt. In response, the U.S. Congress passed the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA), which established a Financial Oversight and Management Board (Oversight Board) to provide fiscal oversight. Title III of PROMESA provides Puerto Rico with a judicial process for restructuring its debt similar to, but not identical to, Chapter 9 of the U.S. Bankruptcy Code, including a stay of debtholder litigation. In 2017, the Oversight Board approved and certified the filing in the U.S. District Court for the District of Puerto Rico of a voluntary petition under Title III of PROMESA for the government of Puerto Rico and certain of its governmental entities, including the Puerto Rico Electric Power Authority, which is currently undergoing a privatization process of its transmission and distribution infrastructure. Under PROMESA, other Title III filings for additional government entities may occur, further complicating Puerto Rico's already uncertain fiscal stability. In June 2019, in response to legal challenges, the U.S. Supreme Court ruled in favor of PROMESA and confirmed the constitutionality of the appointment process.

Each year since 2017, the Oversight Board has updated Puerto Rico's fiscal plans imposing significant expense reductions. Each plan has stressed the need for fiscal and structural reforms to address Puerto Rico's challenging economic and demographic trends. There is pending litigation between the Government of Puerto Rico and the Oversight Board with regards to the Oversight Board's powers under PROMESA and authority to review and prevent the enforcement of government-approved legislation. This litigation, currently underway in the Title III Court, may impact how and when Puerto Rico will eventually restructure its debt and achieve fiscal and economic stability.

While the government and the Oversight Board have authorized emergency relief packages due to the COVID-19 pandemic, it is uncertain how, or the degree to which, the pandemic will impact Puerto Rico's fiscal and structural reforms and its economy. In addition, the 2017 Tax Act no longer permits deferral of U.S. taxation on Puerto Rico earnings, although these earnings generally will be taxed in the United States at a reduced rate. Given Puerto Rico's challenged economy, disaster recovery needs and impact from the COVID-19 pandemic, it may be difficult for Puerto Rico to sustain or grow its manufacturing base, which contributes significantly to Puerto Rico's economy, due to competition from other locations subject to similar levels of taxation.

While PROMESA and the actions above continue to be important factors in moving Puerto Rico toward economic stability, Puerto Rico's ongoing economic and demographic trend challenges and political situation, the effects of natural disasters, the COVID-19 pandemic, and the effects of the 2017 Tax Act or other potential tax law changes have negatively affected, and may in the future negatively affect, the territorial government's provision of utilities or other services in Puerto Rico that we use in the operation of our business and could create the potential for increased taxes or fees to operate in Puerto Rico, result in a migration of workers from Puerto Rico to the mainland United States, or make it more expensive or difficult for us to operate in Puerto Rico. These factors could have a material adverse effect on our ability to supply our products, on our business and on our product sales.

We rely on third-party suppliers for certain of our raw materials, medical devices and components.

We rely on unaffiliated third-party suppliers for certain raw materials, medical devices and components necessary for the manufacturing of our commercial and clinical products. Certain of those raw materials, medical devices and components are proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug applications with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until the regulatory agency approved such supplier. For example, Scandinavian Health Limited Group is our single source of SureClick® autoinjectors for Repatha®, ENBREL, Aimovig®, AMGEVITA™ and Aranesp®. Also, certain of the raw materials required in the commercial and clinical manufacturing of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues, bovine serum and human serum albumin.

Among the reasons we may be unable to obtain these raw materials, medical devices and components include:

- regulatory requirements or action by regulatory agencies or others;
- adverse financial or other strategic developments at or affecting the supplier, including bankruptcy;
- unexpected demand for or shortage of raw materials, medical devices or components;
- failure to comply with our quality standards which results in quality and product failures, product contamination and/or recall;
- a material shortage, contamination, recall and/or restrictions on the use of certain biologically derived substances or other raw materials;
- discovery of previously unknown or undetected imperfections in raw materials, medical devices or components;
- cyberattacks on supplier systems; and
- labor disputes or shortages, including from the effects of health emergencies (such as novel viruses or pandemics such as the one we are currently experiencing with COVID-19) and natural disasters.

For example, in prior years we have experienced shortages in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility. Further quality issues that result in unexpected additional demand for certain components may lead to shortages of required raw materials or components (such as we have experienced with EPOGEN® glass vials). We may experience similar or other shortages in the future resulting in delayed shipments, supply constraints, clinical trial delays, contract disputes and/or stock-outs of our products. These or other similar events could negatively affect our ability to satisfy demand for our products or conduct clinical trials, which could have a material adverse effect on our product sales, business and results of operations.

Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

Manufacturing biologic and small molecule human therapeutic products is difficult, complex and highly regulated. We manufacture many of our commercial products and product candidates internally. In addition, we currently use third-party contract manufacturers to produce, or assist in the production of, a number of our products, and we currently use contract manufacturers to produce, or assist in the production of, a number of our late-stage product candidates and drug delivery devices. See Item 1. Business—Manufacturing, Distribution and Raw Materials—Manufacturing. Our ability to adequately and timely manufacture and supply our products (and product candidates to support our clinical trials) is dependent on the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers, which may be affected by:

- capacity of manufacturing facilities;
- contamination by microorganisms or viruses, or foreign particles from the manufacturing process;

- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of health emergencies (such as novel viruses or pandemics such as the one we are currently experiencing with COVID-19) or natural disasters;
- compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs and production success rates and yields;
- updates of manufacturing specifications;
- contractual disputes with our suppliers and contract manufacturers;
- timing and outcome of product quality testing;
- power failures and/or other utility failures;
- cyberattacks on supplier systems;
- breakdown, failure, substandard performance or improper installation or operation of equipment (including our information technology systems and network-connected control systems or those of our contract manufacturers or third-party service providers); and/or
- delays in the ability of the FDA or foreign regulatory agencies to provide us necessary reviews, inspections and approvals, including as a result of a subsequent extended U.S. federal or other government shutdowns.

If any of these or other problems affect production in one or more of our facilities or those of our third-party contract manufacturers, or if we do not accurately forecast demand for our products or the amount of our product candidates required in clinical trials, we may be unable to start or increase production in our unaffected facilities to meet demand. If the efficient manufacture and supply of our products or product candidates is interrupted, we may experience delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends, contract disputes and/or recalls of our products. From time to time we have initiated recalls of certain lots of our products. For example, in July 2014 we initiated a voluntary recall of an Aranesp® lot distributed in the EU after particles were detected in a quality control sample following distribution of that lot, and in April 2018 we initiated a precautionary recall of two batches of Vectibix® distributed in Switzerland after potential crimping defects were discovered in the metal seals on some product vials. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could have a material adverse effect on our product sales, business and results of operations.

Our manufacturing processes, those of our third-party contract manufacturers and those of certain of our third-party service providers must undergo regulatory approval processes and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build, validate and license another manufacturing plant, and it can take longer than three years to qualify and license a new contract manufacturer or service provider. If we elect or are required to make changes to our manufacturing processes because of new regulatory requirements, new interpretations of existing requirements or other reasons, this could increase our manufacturing costs and result in delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends or contract negotiations or disputes. Such manufacturing challenges may also occur if our existing contract manufacturers are unable or unwilling to timely implement such changes, or at all.

In addition, regulatory agencies conduct routine monitoring and conduct inspections of our manufacturing facilities and processes as well as those of our third-party contract manufacturers and service providers. If regulatory authorities determine that we or our third-party contract manufacturers or certain of our third-party service providers have violated regulations, they may mandate corrective actions and/or issue warning letters, or even restrict, suspend or revoke our prior approvals, prohibiting us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. See also *Our current products and products in development cannot be sold without regulatory approval.* Such issues may also delay the approval of product candidates we have submitted for regulatory review, even if such product candidates are not directly related to the products, devices or processes at issue with regulators. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis, or at all. If we or our third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers fail to supply materials, products or services to us, we may experience delayed shipments, delays in our clinical trials, supply constraints, contract disputes, stock-outs and/or recalls of our products. Additionally, we distribute a substantial volume of our commercial products through our primary distribution centers in Louisville, Kentucky for the United States and in Breda, Netherlands for Europe and much of the rest of the world. We also conduct most of the labeling and packaging of our products distributed in Europe and much of the rest of the world in Breda. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics centers, our third-party logistics providers and our labeling and packaging facility in Breda. Further, we rely on commercial transportation, including air and sea freight, for the distribution of our products to our customers, which may be negatively affected by natural disasters, security threats and/or the ongoing COVID-19 pandemic.

There have also been legislative and administrative proposals seeking to incentivize greater drug manufacturing in the United States with the stated goal of improving supply reliability in the United States. For example, on August 6, 2020, the previous Administration issued an Executive Order aimed at boosting domestic production of essential medicines, medical countermeasures, and critical inputs titled "Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs are Made in the United States." Additionally, one legislative proposal would prohibit the U.S. Department of Veterans Affairs from purchasing certain drugs that have active pharmaceutical ingredients manufactured outside the United States. While we perform a substantial majority of our commercial manufacturing activities in the United States, including in the U.S. territory of Puerto Rico, and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California, the passage of such legislation could result in foreign governments enacting retaliatory legislation or regulatory actions, which may have an adverse effect on our product sales, business and results of operations.

GENERAL RISK FACTORS

Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Our operations and performance have been, and may continue to be, affected by global economic conditions. The economic downturn resulting from the COVID-19 pandemic has precipitated a global recession which may be of an extended duration. Additionally, financial pressures may cause government or other third-party payers to more aggressively seek cost containment measures. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability*. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships may also affect patients' ability to afford health care as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to reduced demand for our products, which could have a material adverse effect on our product sales, business and results of operations. Economic conditions may also adversely affect the ability of our distributors, customers and suppliers to obtain the liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Although we monitor our distributors', customers' and suppliers' financial condition and their liquidity to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could have a material adverse effect on our product sales, business and results of operations. A significant worsening of global economic conditions could materially increase these risks facing us.

We maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our Consolidated Balance Sheets. The global spread of COVID-19 has also led to disruption and volatility in the global capital markets. We have certain assets, including equity investments, that are exposed to market fluctuations that could, in a sustained or recurrent series of market disruptions, result in impairments. The value of our investments may also be adversely affected by interest rate fluctuations, downgrades in credit ratings, illiquidity in the capital markets and other factors that may result in other-than-temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on sales of investments.

Our stock price is volatile.

Our stock price, like that of our peers in the biotechnology and pharmaceutical industries, is volatile. Our revenues and operating results may fluctuate from period to period for a number of reasons. Events such as a delay in product development, changes to our expectations or strategy or even a relatively small revenue shortfall may cause financial results for a period to be below our expectations or projections. As a result, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Announcements or discussions, including via social media channels, of possible restrictive actions by government or private payers that would negatively affect our business or industry if ultimately enacted or adopted may also cause our stock price to fluctuate, whether or not such restrictive actions ever actually occur. Similarly, actual or perceived safety issues with our products or similar products or unexpected clinical trial results can have an immediate and rapid effect on our stock price, whether or not our operating results are materially affected.

We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The capital and credit markets may experience extreme volatility and disruption, which may lead to uncertainty and liquidity issues for both borrowers and investors. For example, early in 2020, there were significant disruptions in the commercial paper market and several borrowers were unable to obtain funding at normal rates or maturities, which resulted in a significant increase in draws of corporate credit lines with banks. Similarly, the bond markets experienced extreme volatility in terms of interest rates and credit spreads, with several days without new issuances of corporate bonds. We expect to access the capital markets, from time to time, to supplement our existing funds and cash generated from operations in satisfying our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we strategically plan to pursue, including acquisitions and licensing activities. In the event of adverse capital and credit market conditions, we may be unable to obtain capital market financing on similar favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Changes in credit ratings issued by nationally recognized credit-rating agencies could adversely affect our ability to obtain capital market financing and the cost of such financing and have an adverse effect on the market price of our securities.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. **PROPERTIES**

As of December 31, 2020, we owned or leased approximately 180 properties. The locations and primary functions of significant properties are summarized in the following tables:

U.S. Location:	Manufacturing	Administrative	R&D	Sales & marketing	Warehouse	Distribution center
Thousand Oaks, CA*	✓	✓	✓	✓	✓	✓
San Francisco, CA			✓			
Louisville, KY					✓	✓
Cambridge, MA			✓			
Woburn, MA	✓				✓	
Juncos, Puerto Rico	✓	✓			✓	✓
West Greenwich, RI	✓	✓			✓	
Tampa, FL		✓				
Other U.S. cities		✓		✓		

* Corporate headquarters

Ex-U.S. Location:	Manufacturing	Administrative	R&D	Sales & marketing	Warehouse	Distribution center
Brazil	✓	✓		✓	✓	✓
Canada		✓	✓	✓		
China		✓		✓		
Germany		✓	✓	✓		
Iceland		✓	✓			
Ireland	✓	✓		✓	✓	
Japan		✓	✓	✓		
Netherlands	✓	✓		✓	✓	✓
Singapore	✓	✓		✓	✓	
Switzerland		✓		✓		
Turkey	✓	✓		✓	✓	✓
United Kingdom		✓	✓	✓		
Other countries		✓	✓	✓	✓	

Excluded from the information above are (i) undeveloped land and leased properties that have been abandoned and (ii) certain buildings we still own but that are no longer used in our business. There are no material encumbrances on our owned properties.

We believe our facilities are suitable for their intended uses and, in conjunction with our third-party contract manufacturing agreements, provide adequate capacity and are sufficient to meet our expected needs. See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

See Item 1. Business—Manufacturing, Distribution and Raw Materials.

Item 3. **LEGAL PROCEEDINGS**

Certain of the legal proceedings in which we are involved are discussed in Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements and are hereby incorporated by reference.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. **MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Common stock

Our common stock trades on the NASDAQ Global Select Market under the symbol AMGN. As of February 3, 2021, there were approximately 5,336 holders of record of our common stock.

Performance graph

The following graph shows the value of an investment of $100 on December 31, 2015, in each of Amgen common stock, the Amex Biotech Index, the Amex Pharmaceutical Index and Standard & Poor's 500 Index (S&P 500). All values assume reinvestment of the pretax value of dividends and are calculated as of December 31 of each year. The historical stock price performance of the Company's common stock shown in the performance graph is not necessarily indicative of future stock price performance.

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	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020
Amgen (AMGN)	$100.00	$92.45	$113.08	$130.14	$166.09	$162.76
Amex Biotech (BTK)	$100.00	$80.85	$111.42	$111.72	$134.54	$152.81
Amex Pharmaceutical (DRG)	$100.00	$91.66	$106.90	$114.86	$135.96	$147.86
S&P 500 (SPX)	$100.00	$111.95	$136.46	$130.50	$171.57	$203.12

The material in this performance graph is not soliciting material, is not deemed filed with the SEC and is not incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made on, before or after the date of this filing and irrespective of any general incorporation language in such filing.

Stock repurchase program

During the three months and year ended December 31, 2020, we had one outstanding stock repurchase program, under which the repurchasing activity was as follows:

	Total number of shares purchased	Average price paid per share[1]	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program[2]
October 1 - October 31	1,774,922	$ 235.06	1,774,922	$ 3,781,230,811
November 1 - November 30	1,660,605	$ 229.16	1,660,605	$ 3,400,688,112
December 1 - December 31	1,868,786	$ 226.94	1,868,786	$ 2,976,579,948
	5,304,313	$ 230.35	5,304,313	
January 1 - December 31	15,190,194	$ 230.24	15,190,194	

(1) Average price paid per share includes related expenses.

(2) In December 2019, our Board of Directors increased the amount authorized under the stock repurchase program by an additional $4.0 billion.

Dividends

For the years ended December 31, 2020 and 2019, we paid quarterly dividends. We expect to continue to pay quarterly dividends, although the amount and timing of any future dividends are subject to approval by our Board of Directors. Additional information required by this item is incorporated herein by reference to Part IV—Note 16, Stockholders' equity, to the Consolidated Financial Statements.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

Information about securities authorized for issuance under existing equity compensation plans is incorporated by reference from Item 12—Securities Authorized for Issuance Under Existing Equity Compensation Plans.

Item 6. **SELECTED FINANCIAL DATA**

Consolidated Statements of Income Data:	Years ended December 31, 2020	2019	2018	2017	2016
	(In millions, except per-share data)				
Revenues:					
Product sales	$ 24,240	$ 22,204	$ 22,533	$ 21,795	$ 21,892
Other revenues	1,184	1,158	1,214	1,054	1,099
Total revenues	$ 25,424	$ 23,362	$ 23,747	$ 22,849	$ 22,991
Operating expenses:					
Cost of sales	$ 6,159	$ 4,356	$ 4,101	$ 4,069	$ 4,162
Research and development	$ 4,207	$ 4,116	$ 3,737	$ 3,562	$ 3,840
Selling, general and administrative	$ 5,730	$ 5,150	$ 5,332	$ 4,870	$ 5,062
Net income[1]	$ 7,264	$ 7,842	$ 8,394	$ 1,979	$ 7,722
Diluted earnings per share[1]	$ 12.31	$ 12.88	$ 12.62	$ 2.69	$ 10.24
Dividends paid per share	$ 6.40	$ 5.80	$ 5.28	$ 4.60	$ 4.00

Consolidated Balance Sheets Data:	As of December 31, 2020	2019	2018	2017	2016
	(In millions)				
Total assets	$ 62,948	$ 59,707	$ 66,416	$ 79,954	$ 77,626
Total debt[2]	$ 32,986	$ 29,903	$ 33,929	$ 35,342	$ 34,596
Total stockholders' equity[3]	$ 9,409	$ 9,673	$ 12,500	$ 25,241	$ 29,875

(1) In 2017, we recorded a net charge of $6.1 billion as a result of the 2017 Tax Act.

(2) See Part IV—Note 15, Financing arrangements, to the Consolidated Financial Statements, for discussion of our financing arrangements in 2020, 2019 and 2018. In 2017, we issued $4.5 billion of debt and repaid $4.4 billion of debt. In 2016, we issued $7.3 billion of debt and repaid $3.7 billion of debt.

(3) Throughout the five years ended December 31, 2020, we had a stock repurchase program authorized by the Board of Directors, through which we repurchased $3.5 billion, $7.6 billion, $17.9 billion, $3.1 billion and $3.0 billion, respectively, of Amgen common stock.

In addition to the above notes, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, Part IV—Consolidated Financial Statements and accompanying notes as well as previously filed Annual Reports on Form 10-K for further information regarding our consolidated results of operations and financial position for periods reported therein and for known factors that will affect the comparability of future results. Also see Part IV—Note 16, Stockholders' equity, to the Consolidated Financial Statements, for information regarding cash dividends declared per share of common stock for each of the four quarters of 2020, 2019 and 2018. In addition, our Board of Directors declared dividends per share of $1.15 and $1.00, which were paid in each of the four quarters of 2017 and 2016, respectively.

Item 7. **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following management's discussion and analysis (MD&A) is intended to assist the reader in understanding Amgen's business. MD&A is provided as a supplement to, and should be read in conjunction with, our consolidated financial statements and accompanying notes. Our results of operations discussed in MD&A are presented in conformity with U.S. generally accepted accounting principles (GAAP). Amgen operates in one business segment: human therapeutics. Therefore, our results of operations are discussed on a consolidated basis.

Forward-looking statements

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. In addition, we, or others on our behalf, may make forward-looking statements in press releases, written statements or our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Such words as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume" and "continue" as well as variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and they involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in Part I, Item 1A. Risk Factors. We have based our forward-looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecasted by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, earnings per share (EPS), liquidity and capital resources, trends, planned dividends, stock repurchases, collaborations and effects of pandemics. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

Amgen is a biotechnology company committed to unlocking the potential of biology for patients suffering from serious illnesses. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential. In 2020, we celebrated our 40th anniversary, continuing our history of focusing on innovative medicines that have the potential to be first-in-class molecules and that have a large-effect size on serious diseases.

Our principal products—those with the most significant annual commercial sales—are ENBREL, Prolia®, Neulasta®, Otezla®, XGEVA®, Aranesp®, KYPROLIS® and Repatha®. We also market a number of other products, including Nplate®, Vectibix®, MVASI®, Parsabiv®, EPOGEN®, KANJINTI®, BLINCYTO®, Aimovig®, EVENITY®, AMGEVITA™, Sensipar®/Mimpara®, NEUPOGEN®, IMLYGIC®, Corlanor® and AVSOLA®. For additional information about our products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products.

Our strategy includes integrated activities intended to maintain and strengthen our competitive position in the industry. We focus on six commercial areas: inflammation, oncology/hematology, bone health, CV disease, nephrology and neuroscience, and we conduct discovery research primarily in three therapeutic areas: inflammation, oncology/hematology and CV/metabolic diseases. In 2020, we advanced our innovative pipeline, successfully integrated Otezla®, acquired in November 2019, into our inflammation portfolio, advanced our international expansion and continued to provide uninterrupted supply of our medicines globally through the COVID-19 pandemic. We accomplished these objectives while maintaining a strategic and disciplined approach to capital allocation, and advancing our environmental, social and governance efforts.

During the year, while meeting the challenges of a global pandemic and facing increased competition from biosimilars and generics, total product sales increased 9%, driven by volume growth primarily from Otezla®, partially offset by lower net selling prices. Product sales increased 9% and 10% in the United States and rest of the world, respectively. Total operating expenses increased 19%, driven by expenses related to Otezla®.

We continued to advance our pipeline, including sotorasib and tezepelumab—two molecules with respect to which we have achieved positive registration enabling data from our clinical trial activities. We also continued to advance our biosimilar program with the launch of AVSOLA® and the approval of RIABNI™ in the United States. Our biosimilars are expected to launch in new markets throughout 2021. Lastly, we broadened our international reach, particularly in the Asia Pacific region with our investment in and strategic collaboration with BeiGene to expand our oncology presence in China, as well as the establishment of our wholly owned affiliate in Japan.

Cash flows from operating activities totaled $10.5 billion, enabling us to invest in our business while returning capital to shareholders through the payment of cash dividends and stock repurchases. For 2020, we increased our quarterly cash dividend by 10% to $1.60 per share of common stock. In December 2020, we declared a cash dividend of $1.76 per share of common stock for the first quarter of 2021, an increase of 10% for this period, to be paid in March 2021. We also repurchased 15.2 million shares of our common stock throughout 2020, at an aggregate cost of $3.5 billion. During the year, we had proceeds from the issuance of debt of $8.9 billion and repayments of debt of $6.5 billion. In addition, we exchanged some of our higher interest rate debt for newly issued debt with a lower interest rate and a later maturity date.

Amgen's approach to, and investment in, human capital resource management is directed at attracting, motivating and retaining talent to tackle the challenges of running an enterprise focused on the discovery, development, and commercialization of innovative medicines. Our compensation, benefits and development programs are designed to encourage performance, promote accountability and adherence to Company values, and in alignment with the interests of the Company's shareholders. Further, we believe that a diverse and inclusive culture fosters innovation, which supports our ability to serve patients. We also believe our global presence is strengthened by having a workforce that reflects the diversity of the patients we serve. It is with these beliefs in mind that we have continued to strengthen and grow our culture of diversity, inclusion and belonging. Our internal efforts include, in 2019, establishing a Diversity, Inclusion and Belonging Council. We are engaging in activities and setting goals to improve our focus on diversity, inclusion and belonging. For further information on these and other efforts, see Part I, Item 1. Business—Human Capital Resources.

We have a long-standing ambition to be environmentally responsible, and we regularly set targets to challenge ourselves to deliver further improvements. In 2020, we met or exceeded our environmental sustainability targets set out in 2013 that called for reducing fleet carbon output by up to 20%, facility carbon output by 10%, water consumption by 10% and waste disposal by 35%[2]. We achieved our 2020 targets while growing revenues, increasing production capacity, and expanding to more than 100 countries over the same 2013 to 2020 period. To continue on our path to greater environmental sustainability, in January 2021 we announced a new set of long-term environmental targets to achieve by 2027, including achieving carbon neutrality, reducing water consumption by 40% and reducing waste disposed by 75%.

Our long-term success depends to a great extent on our ability to continue to discover, develop and commercialize innovative products and acquire or collaborate on therapies currently in development by other companies. We must develop new products to achieve revenue growth and to offset revenue losses when products lose their exclusivity or when competing products are launched. Certain of our products face increasing pressure from competition, including biosimilars and generics. For additional information, including information on the expirations of patents for various products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents, and Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We devote considerable resources to R&D activities, but successful product development in the biotechnology industry is highly uncertain. We also face increasing regulatory scrutiny of safety and efficacy both before and after products launch.

Rising healthcare costs and uncertain economic conditions continue to pose challenges to our business, including increasing pressure by third-party payers, such as governments and private payers, to reduce healthcare expenditures. As a result of public and private healthcare-provider focus, the industry continues to experience significant pricing pressures and other cost containment measures. Finally, wholesale and end-user buying patterns can affect our product sales. These effects can cause fluctuations in quarterly product sales and have generally not been significant when comparing full-year product performance to the prior year. See Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products and Part I, Item 1A. Risk Factors for further discussion of certain factors that could impact our future product sales.

COVID-19 pandemic

The COVID-19 pandemic has had a moderate impact to our business in 2020. Since the onset of the pandemic in early 2020, we have been carefully monitoring its impact on our global operations. We have taken appropriate steps to minimize the risk to our employees. A significant number of our employees have been working remotely, with the exception of certain staff that require access to our manufacturing and laboratory research facilities, in accordance with applicable government health and safety protocols and guidance issued in response to the COVID-19 pandemic. To date, our remote working arrangements have not significantly affected our ability to maintain critical business operations, and we have not experienced disruptions or shortages of our supply of medicines.

Since the beginning of the COVID-19 pandemic, we have seen changes in demand trends for some of our products, including lower demand for certain products as continuing patient access to those products has been affected by COVID-19, particularly in the early phases of the pandemic. For example, near the end of March, we began to observe a decline in sales of Prolia®, as elderly patients, who are relatively more vulnerable to COVID-19, avoided doctors' offices. Demand has since recovered to varying degrees by product as local conditions improved in certain geographies that opened after an initial improvement in COVID-19 infection rates, allowing patients to resume receiving their treatments. During the second half of the year, our own efforts remain focused on assisting patients with improving their continuity of care to increase product access as compared to what they experienced during the earlier stages of the pandemic. Recently, higher rates of infection have been observed in certain geographies, including the United States and Europe, which may further restrict demand, similar to early phases of the pandemic. As a result, we expect to see continued volatility through at least the duration of the pandemic as governments respond to current local conditions.

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[2] Represents reductions against established baselines, taking into account only verified reduction projects, and does not take into account changes associated with contraction or expansion of the company.

The majority of clinical trials that were paused at the onset of the pandemic to ensure subject safety or data integrity have resumed. Study enrollment was affected negatively the most in the second quarter of the year and by the end of 2020 resumed to around pre-pandemic levels. However, going forward COVID-19 infection rates and related vaccination activities may impact future study enrollment. We continuously monitor our ability for study enrollment on an institution by institution basis and reevaluate the status of studies, pausing when uncertainty arises with regard to the trial sites' ability to ensure safety or data integrity. We remain focused on supporting our active clinical sites in providing care for these patients and in providing investigational drug supply. In addition, our R&D organization is supporting efforts to combat the COVID-19 pandemic in a number of ways, including by (i) working to support production of therapeutic antibodies that could diminish the impact of COVID-19 on patients, (ii) joining a public–private partnership between leading companies in our industry and U.S. government health agencies to develop a strategy for a coordinated research response and (iii) participating in platform studies to investigate treatments in adult patients hospitalized with severe COVID-19 infections.

We continue to believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital, capital expenditures and debt service requirements as well as to engage in the capital-return and other business initiatives that we plan to strategically pursue. For a discussion of the risks presented by the COVID-19 pandemic to our results, see Part I, Item 1A. Risk Factors of this Form 10-K.

Selected Financial Information

The following is an overview of our results of operations (in millions, except percentages and per-share data):

	Year ended December 31, 2020	Change	Year ended December 31, 2019
Product sales:			
U.S.	$ 17,985	9 %	$ 16,531
Rest-of-world (ROW)	6,255	10 %	5,673
Total product sales	24,240	9 %	22,204
Other revenues	1,184	2 %	1,158
Total revenues	$ 25,424	9 %	$ 23,362
Operating expenses	$ 16,285	19 %	$ 13,688
Operating income	$ 9,139	(6)%	$ 9,674
Net income	$ 7,264	(7)%	$ 7,842
Diluted EPS	$ 12.31	(4)%	$ 12.88
Diluted shares	590	(3)%	609

In the following discussion of changes in product sales, any reference to unit demand growth or decline refers to changes in the purchases of our products by healthcare providers (such as physicians or their clinics), dialysis centers, hospitals and pharmacies. In addition, any reference to increases or decreases in inventory refers to changes in inventory held by wholesaler customers and end users (such as pharmacies).

Total product sales increased for 2020, primarily driven by unit demand increases from newer brands including Otezla®, acquired in November 2019, MVASI®, KANJINTI® and Repatha®. These unit demand increases were partially offset by declines in net selling prices for certain products, unit demand declines for mature brands that face biosimilar or generic competition and the effects of the COVID-19 pandemic. For 2021, we expect that net selling prices will continue to decline. We also expect increasing competition against our biosimilar products. Further, the first quarter historically represents the lowest product sales quarter for the year, in part, due to plan changes, insurance reverifications and higher co-pay expenses as U.S. patients work through deductibles, particularly for our pharmacy benefit products.

During the initial stages of the COVID-19 pandemic, we experienced changes in demand trends for some of our products. The pandemic interrupted many physician–patient interactions, which led to delays in diagnosis and treatment, with varying degrees of impact across our portfolio. In general, sales of negatively affected products fell the most in the early part of the second quarter, with product demand beginning to show some recovery in the second half of the year but still below pre-pandemic levels. Nevertheless, given the increased intensity exiting 2020 and the unpredictable nature of the pandemic, we expect there could be intermittent disruptions in physician–patient interactions going forward, and thus we continue to expect quarter-to-quarter variability. See Part I, Item 1A. Risk Factors of this Form 10-K.

In addition, other changes in the healthcare ecosystem introduce variability into product sales trends. For example, changes in U.S. employment could lead to changes to the insured population, with growth in Medicaid enrollees and uninsured individuals having a negative impact on revenues. Overall, uncertainty has increased around the timing and magnitude of our sales during the COVID-19 pandemic.

Other revenues increased for 2020, primarily driven by higher royalties.

Operating expenses increased for 2020, primarily driven by acquisition- and commercial-related expenses for Otezla®.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is partially offset by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure,

primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material in 2020, 2019 or 2018.

Results of Operations

Product sales

Worldwide product sales were as follows (dollar amounts in millions):

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
ENBREL	$ 4,996	(4)%	$ 5,226	4 %	$ 5,014
Prolia®	2,763	3 %	2,672	17 %	2,291
Neulasta®	2,293	(29)%	3,221	(28)%	4,475
Otezla®	2,195	*	178	N/A	—
XGEVA®	1,899	(2)%	1,935	8 %	1,786
Aranesp®	1,568	(9)%	1,729	(8)%	1,877
KYPROLIS®	1,065	2 %	1,044	8 %	968
Repatha®	887	34 %	661	20 %	550
Other products	6,574	19 %	5,538	(1)%	5,572
Total product sales	$ 24,240	9 %	$ 22,204	(1)%	$ 22,533
Total U.S.	$ 17,985	9 %	$ 16,531	(5)%	$ 17,429
Total ROW	6,255	10 %	5,673	11 %	5,104
Total product sales	$ 24,240	9 %	$ 22,204	(1)%	$ 22,533

* Change in excess of 100%.

Future sales of our products will depend in part on the factors discussed in the Overview, Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition, in Part I, Item 1A. Risk Factors, and any additional factors discussed in the individual product sections below. In addition, for a list of our products' significant competitors, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition.

ENBREL

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
ENBREL — U.S.	$ 4,855	(4)%	$ 5,050	5 %	$ 4,807
ENBREL — Canada	141	(20)%	176	(15)%	207
Total ENBREL	$ 4,996	(4)%	$ 5,226	4 %	$ 5,014

The decrease in ENBREL sales for 2020 was driven by lower unit demand and net selling price, partially offset by favorable changes to estimated sales deductions and inventory. Consistent with prior periods, ENBREL has continued to lose market share, and this decline has been compounded by a reduction in the growth rate of the rheumatology market as a result of COVID-19. For 2021, we expect ENBREL to follow the historic pattern of lower sales in the first quarter relative to subsequent quarters due to the impact of benefit plan changes, insurance reverification and increase co-pay expenses as U.S. patients work through deductibles. In addition, for 2021, we expect volume and net selling price declines to continue.

The increase in ENBREL sales for 2019 was primarily driven by favorable changes to estimated sales deductions and an increase in net selling price, partially offset by lower unit demand.

In April 2019, the FDA approved a second biosimilar version of ENBREL, and we are involved in patent litigations with the two companies seeking to market their FDA-approved biosimilar versions of ENBREL. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. Companies with approved

biosimilar versions of ENBREL may seek to enter the U.S. market if we are not successful in our litigations, or even earlier. Other companies are also developing proposed biosimilar versions of ENBREL.

Prolia®

Total Prolia® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Prolia® — U.S.	$ 1,830	3 %	$ 1,772	18 %	$ 1,500
Prolia® — ROW	933	4 %	900	14 %	791
Total Prolia®	$ 2,763	3 %	$ 2,672	17 %	$ 2,291

Disruptions in patient visits as a result of the COVID-19 pandemic affected demand during 2020 by altering the timing of patients receiving their semiannual doses and by lowering the diagnosis of osteoporosis in new patients. This deceleration of demand has softened the historical growth rates and altered demand patterns of Prolia® experienced in years prior to the pandemic. For 2021, historical demand patterns may continue to be impacted by the pandemic.

The increase in global Prolia® sales for 2020 was driven by higher unit demand and net selling price.

The increase in global Prolia® sales for 2019 was driven by higher unit demand.

Neulasta®

Total Neulasta® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Neulasta® — U.S.	$ 2,001	(29)%	$ 2,814	(27)%	$ 3,866
Neulasta® — ROW	292	(28)%	407	(33)%	609
Total Neulasta®	$ 2,293	(29)%	$ 3,221	(28)%	$ 4,475

The decreases in global Neulasta® sales for 2020 and 2019 were driven by the impact of biosimilar competition on net selling price and unit demand. Neulasta® sales included a $98 million order from the U.S. government in the first quarter of 2019.

We have increased competition in the United States and Europe as a result of biosimilar versions of Neulasta®, which has had and will continue to have a material adverse impact on sales. We also expect other biosimilar versions to be approved in the future. For a discussion of ongoing patent litigations related to these and other biosimilars, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Otezla®

Total Otezla® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Otezla® — U.S.	$ 1,790	*	$ 139	N/A	$ —
Otezla® — ROW	405	*	39	N/A	—
Total Otezla®	$ 2,195	*	$ 178	N/A	$ —

* Change in excess of 100%.

Otezla® was acquired on November 21, 2019, and generated $2.2 billion and $178 million in global sales for the years ended December 31, 2020 and 2019, respectively. For 2021, we expect Otezla® to follow the historic pattern of lower sales in the first quarter relative to subsequent quarters due to the impact of benefit plan changes, insurance reverification and increase co-pay expenses as U.S. patients work through deductibles.

For a discussion of ongoing litigation related to Otezla®, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

XGEVA®

Total XGEVA® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
XGEVA® — U.S.	$ 1,405	(4)%	$ 1,457	9 %	$ 1,338
XGEVA® — ROW	494	3 %	478	7 %	448
Total XGEVA®	$ 1,899	(2)%	$ 1,935	8 %	$ 1,786

The decrease in global XGEVA® sales for 2020 was driven by lower unit demand as a result of the COVID-19 pandemic.

The increase in global XGEVA® sales for 2019 was primarily driven by higher unit demand.

Aranesp®

Total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Aranesp® — U.S.	$ 629	(17)%	$ 758	(20)%	$ 942
Aranesp® — ROW	939	(3)%	971	4 %	935
Total Aranesp®	$ 1,568	(9)%	$ 1,729	(8)%	$ 1,877

The decrease in global Aranesp® sales for 2020 was driven by declines in net selling price and unit demand.

The decrease in global Aranesp® sales for 2019 was primarily driven by the impact of competition on unit demand in the United States.

Aranesp® faces competition from a long-acting ESA. Aranesp® also faces competition from a biosimilar version of EPOGEN®. For 2021, we expect that sales will continue to decline due to short- and long-acting competition.

KYPROLIS®

Total KYPROLIS® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
KYPROLIS® — U.S.	$ 710	9 %	$ 654	12 %	$ 583
KYPROLIS® — ROW	355	(9)%	390	1 %	385
Total KYPROLIS®	$ 1,065	2 %	$ 1,044	8 %	$ 968

The increase in global KYPROLIS® sales for 2020 was primarily driven by an increase in net selling price and favorable changes in inventory, partially offset by lower unit demand.

The increase in global KYPROLIS® sales for 2019 was primarily driven by higher unit demand.

We are engaged in litigation with two companies that are challenging certain of our patents related to KYPROLIS® and that are seeking to market generic carfilzomib products. Separately, we have entered into confidential settlement agreements with other companies developing generic carfilzomib products, and the court has entered consent judgments enjoining those companies from infringing certain of our patents, subject to terms of the confidential settlement agreements. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. The FDA reported that it has granted tentative or final approval to Abbreviated New Drug Applications (ANDAs) for generic carfilzomib products filed by a number of companies for generic carfilzomib

products. The date of approval of those ANDAs for generic carfilzomib products is governed by the Hatch-Waxman Act and any applicable settlement agreements between the parties.

Repatha®

Total Repatha® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Repatha® — U.S.	$ 459	22 %	$ 376	5 %	$ 358
Repatha® — ROW	428	50 %	285	48 %	192
Total Repatha®	$ 887	34 %	$ 661	20 %	$ 550

The increases in global Repatha® sales for 2020 and 2019 were driven by higher unit demand, partially offset by lower net selling price. The decrease to the Repatha® net selling price in 2020 was the result of contracting changes to improve Medicare Part D patient access.

For a discussion of ongoing litigation related to Repatha®, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Other products

Other product sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Nplate® — U.S.	$ 485	1 %	$ 480	10 %	$ 438
Nplate® — ROW	365	16 %	315	13 %	279
Vectibix® — U.S.	342	8 %	316	10 %	288
Vectibix® — ROW	469	10 %	428	6 %	403
MVASI® — U.S.	656	*	121	N/A	—
MVASI® — ROW	142	*	6	N/A	—
Parsabiv® — U.S.	605	10 %	550	82 %	302
Parsabiv® — ROW	111	39 %	80	*	34
EPOGEN® — U.S.	598	(31)%	867	(14)%	1,010
KANJINTI® — U.S.	475	*	118	N/A	—
KANJINTI® — ROW	92	(15)%	108	*	44
BLINCYTO® — U.S.	231	31 %	176	31 %	134
BLINCYTO® — ROW	148	9 %	136	42 %	96
Aimovig® — U.S.	378	24 %	306	*	119
EVENITY® — U.S.	191	*	42	N/A	—
EVENITY® — ROW	159	8 %	147	N/A	—
AMGEVITA™ — ROW	331	54 %	215	*	11
Sensipar® — U.S.	92	(63)%	252	(82)%	1,436
Sensipar®/Mimpara® — ROW	196	(34)%	299	(12)%	338
NEUPOGEN® — U.S.	144	(19)%	178	(20)%	223
NEUPOGEN® — ROW	81	(6)%	86	(39)%	142
Other — U.S.	109	4 %	105	24 %	85
Other — ROW	174	(16)%	207	9 %	190
Total other product sales	$ 6,574	19 %	$ 5,538	(1)%	$ 5,572
Total U.S. — other products	$ 4,306	23 %	$ 3,511	(13)%	$ 4,035
Total ROW — other products	2,268	12 %	2,027	32 %	1,537
Total other product sales	$ 6,574	19 %	$ 5,538	(1)%	$ 5,572

* Change in excess of 100%.

Operating expenses

Operating expenses were as follows (dollar amounts in millions):

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Operating expenses:					
Cost of sales	$ 6,159	41 %$	4,356	6 %$	4,101
% of product sales	25.4 %		19.6 %		18.2 %
% of total revenues	24.2 %		18.6 %		17.3 %
Research and development	$ 4,207	2 %$	4,116	10 %$	3,737
% of product sales	17.4 %		18.5 %		16.6 %
% of total revenues	16.5 %		17.6 %		15.7 %
Selling, general and administrative	$ 5,730	11 %$	5,150	(3)%$	5,332
% of product sales	23.6 %		23.2 %		23.7 %
% of total revenues	22.5 %		22.0 %		22.5 %
Other	$ 189	* $	66	(79)%$	314

* Change in excess of 100%.

Cost of sales

Cost of sales increased to 24.2% of total revenues for 2020, primarily driven by the amortization of expenses related to our acquisition of Otezla®, and higher royalty expenses and profit share, partially offset by lower manufacturing costs.

Cost of sales increased to 18.6% of total revenues for 2019, primarily driven by unfavorable product mix and amortization of intangible assets as a result of our acquisition of Otezla®, partially offset by lower royalties and lower manufacturing costs.

Research and development

The Company groups all of its R&D activities and related expenditures into three categories: (i) research and early pipeline, (ii) later-stage clinical programs and (iii) marketed products. These categories are described below:

Category	Description
Research and early pipeline	R&D expenses incurred in activities substantially in support of early research through the completion of phase 1 clinical trials, including drug discovery, toxicology, pharmacokinetics and drug metabolism, and process development
Later-stage clinical programs	R&D expenses incurred in or related to phase 2 and phase 3 clinical programs intended to result in registration of a new product or a new indication for an existing product primarily in the United States or the EU
Marketed products	R&D expenses incurred in support of the Company's marketed products that are authorized to be sold primarily in the United States or the EU. Includes clinical trials designed to gather information on product safety (certain of which may be required by regulatory authorities) and their product characteristics after regulatory approval has been obtained, as well as the costs of obtaining regulatory approval of a product in a new market after approval in either the United States or the EU has been obtained

R&D expense by category was as follows (in millions):

	Years ended December 31,		
	2020	2019	2018
Research and early pipeline	$ 1,405	$ 1,649	$ 1,201
Later-stage clinical programs	1,365	1,062	1,034
Marketed products	1,437	1,405	1,502
Total R&D expense	$ 4,207	$ 4,116	$ 3,737

The increase in R&D expense for 2020 was driven by higher spend for later-stage clinical programs, including sotorasib, biosimilar programs and Otezla®, and higher spend for Otezla® included in marketed-product support. These increases were partially offset by recoveries from our collaboration with BeiGene that reduced expenses in later-stage clinical programs and in research and early pipeline, and lower spend in certain oncology programs included in research and early pipeline.

The increase in R&D expense for 2019 was primarily driven by higher spend in research and early pipeline in support of our oncology programs, partially offset by lower marketed-product support.

Selling, general and administrative

The increase in Selling, general and administrative (SG&A) expense for 2020 was driven by investments in certain marketed products, primarily Otezla®, and preparation for product launches, partially offset by a reduction in conference-related expenses due to the impact of COVID-19.

The decrease in SG&A expense for 2019 was primarily driven by lower general and administrative expenses, the end of certain amortization charges in 2018 and lower spend for launched and marketed products, partially offset by spending for Otezla® commercial-related expenses.

Other

Other operating expenses for 2020 primarily consisted of legal settlement expenses.

Other operating expenses for 2019 included $47 million in restructuring costs.

Other operating expenses for 2018 included a $330 million impairment charge associated with an IPR&D asset and a $42 million favorable net change in the fair values of contingent consideration liabilities. See Part IV—Note 17, Fair value measurement, to the Consolidated Financial Statements.

Nonoperating expenses/income and income taxes

Nonoperating expenses/income and income taxes were as follows (dollar amounts in millions):

	Years ended December 31,		
	2020	2019	2018
Interest expense, net	$ 1,262	$ 1,289	$ 1,392
Interest and other income, net	$ 256	$ 753	$ 674
Provision for income taxes	$ 869	$ 1,296	$ 1,151
Effective tax rate	10.7 %	14.2 %	12.1 %

Interest expense, net

The decrease in Interest expense, net, for 2020 was primarily due to lower LIBOR rates on debt for which we effectively pay a variable rate of interest, partially offset by net costs associated with the early retirement of debt.

The decrease in Interest expense, net, for 2019 was primarily due to a reduction in outstanding long-term debt as a result of maturities in 2019.

Interest and other income, net

The decrease in Interest and other income, net, for 2020 was primarily due to reduced interest income as a result of lower average cash balances and a decline in interest yields and losses incurred in connection with our BeiGene investment, partially offset by gains recognized on our investments in publicly traded equity securities and limited partnerships. We may continue to recognize losses in connection with our BeiGene investment in 2021. See Part IV—Note 9, Investments, to the Consolidated Financial Statements.

The increase in Interest and other income, net, for 2019 was primarily due to net gains on sales of investments in interest-bearing securities liquidated to fund our acquisition of Otezla® and our investment in BeiGene compared with losses in the prior year, partially offset by reduced interest income as a result of lower average cash balances and a gain recognized in connection with our acquisition of Kirin-Amgen, Inc. (K-A), in the first quarter of 2018. See Part IV—Note 2, Acquisitions, to the Consolidated Financial Statements.

Income taxes

The decrease in our effective tax rate for 2020 compared with 2019 was primarily driven by favorable items, including audit settlements, adjustments to prior year tax liabilities, lower interest expense on uncertain tax positions and amortization related to the Otezla® acquisition, partially offset by changes in valuation allowance.

The increase in our effective tax rate for 2019 compared with 2018 was primarily driven by a prior-year tax benefit associated with intercompany sales under U.S. corporate tax reform.

In March and December 2020, in response to the COVID-19 pandemic, the CARES Act and the Consolidated Appropriations Act, 2021, were passed into law and provide additional economic stimulus to address the impact of the COVID-19 pandemic. We do not expect any significant benefit to our income tax provision as a result of this legislation.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010, 2011 and 2012 proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. However, we have been unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a Notice of Deficiency which we would expect to vigorously contest through the judicial process. In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagree with the 2013, 2014 and 2015 proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. The IRS audit for years 2016, 2017 and 2018 is expected to start in the near term. We are also currently under examination by a number of other state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our consolidated financial statements.

See Summary of Critical Accounting Policies—Income taxes, and Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

Financial Condition, Liquidity and Capital Resources

Selected financial data was as follows (in millions):

	December 31,	
	2020	2019
Cash, cash equivalents and marketable securities	$ 10,647	$ 8,911
Total assets	$ 62,948	$ 59,707
Current portion of long-term debt	$ 91	$ 2,953
Long-term debt	$ 32,895	$ 26,950
Stockholders' equity	$ 9,409	$ 9,673

Cash, cash equivalents and marketable securities

We have global access to our $10.6 billion balance of cash, cash equivalents and marketable securities. The primary objective of our investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

Capital allocation

Consistent with the objective to optimize our capital structure, we deploy our accumulated cash balances in a strategic manner and consider a number of alternatives, including strategic transactions (including those that expand our portfolio of products in areas of therapeutic interest), repayment of debt, payment of dividends and stock repurchases.

We intend to continue to invest in our business while returning capital to stockholders through the payment of cash dividends and stock repurchases, thereby reflecting our confidence in the future cash flows of our business. The timing and amount of future dividends and stock repurchases will vary based on a number of factors, including future capital requirements for strategic transactions, availability of financing on acceptable terms, debt service requirements, our credit rating, changes to applicable tax laws or corporate laws, changes to our business model and periodic determinations by our Board of Directors that cash dividends and/or stock repurchases are in the best interests of stockholders and are in compliance with applicable laws and the Company's agreements. In addition, the timing and amount of stock repurchases may also be affected by our overall level of cash, stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include private block purchases, tender offers and market transactions.

The Board of Directors declared quarterly cash dividends of $1.60, $1.45 and $1.32 per share of common stock paid in 2020, 2019 and 2018, respectively, an increase of 10% over the prior year in both 2020 and 2019. In December 2020, the Board of Directors declared a cash dividend of $1.76 per share of common stock for the first quarter of 2021, an increase of 10% for this period, to be paid in March 2021.

We also returned capital to stockholders through our stock repurchase program. During 2020, we repurchased $3.5 billion of common stock and had cash settlements of $3.5 billion. In 2019, we repurchased $7.6 billion of common stock and had cash settlements of $7.7 billion. In 2018, we repurchased $17.9 billion of common stock and had cash settlements of $17.8 billion, which included 52.1 million shares of common stock repurchased through a $10.0 billion tender offer. In May 2019 and December 2019, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $5.0 billion and $4.0 billion, respectively. As of December 31, 2020, $3.0 billion remained available under the stock repurchase program.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of December 31, 2020 and 2019. Our accumulated deficit is not anticipated to affect our future ability to operate, repurchase stock, pay dividends or repay our debt given our expected continued profitability and strong financial position.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital, capital expenditure and debt service requirements, our plans to pay dividends and repurchase stock and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt markets and equity markets. See Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business*.

Financing arrangements

The current and noncurrent portions of our long-term borrowings as of December 31, 2020, were $0.1 billion and $32.9 billion, respectively. The current and noncurrent portions of our long-term borrowings as of December 31, 2019, were $3.0 billion and $27.0 billion, respectively. The carrying values of our long-term borrowings are net of fair value adjustments for interest rate swaps and unamortized discounts, premiums and offering costs. As of December 31, 2020, Standard & Poor's Financial Services LLC (S&P), Moody's Investors Service, Inc. (Moody's) and Fitch Ratings, Inc. (Fitch), assigned credit ratings to our outstanding senior notes of A– with a stable outlook, Baa1 with a stable outlook and BBB+ with a stable outlook, respectively, which are considered investment grade. Unfavorable changes to these ratings may have an adverse impact on future financings.

During 2020, we issued debt with an aggregate principal amount of $9.0 billion. During 2019 and 2018, we did not issue any debt or debt securities. During 2020, 2019 and 2018, we repaid debt of $6.5 billion, $4.5 billion and $1.1 billion, respectively. In addition, during 2020, we exchanged $0.7 billion of certain of our outstanding note issuances with $0.9 billion of newly issued notes with a lower interest rate and later maturity date.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the lives of the respective notes. These interest rate swap contracts qualify and are designated as fair value hedges. As of December 31, 2020 and 2019, we had interest rate swap contracts with aggregate notional amounts of $5.9 billion and $9.6 billion, respectively.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts, which effectively convert the interest payments and principal repayment of the respective notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts qualify and are designated as cash flow hedges. As of both December 31, 2020 and 2019, we had cross-currency swap contracts with aggregate notional amounts of $4.8 billion.

As of December 31, 2020, we had a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. During 2020, 2019 and 2018, we did not issue any commercial paper. No commercial paper was outstanding as of December 31, 2020 and 2019.

In 2019, we amended and restated our $2.5 billion syndicated, unsecured, revolving credit agreement, which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $750 million with the agreement of the banks. Each bank that is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest for any amounts borrowed under this facility, based on our current credit rating, at (i) LIBOR plus 1% or (ii) the highest of (A) the syndication agent bank base commercial lending rate, (B) the overnight federal funds rate plus 0.50% or (C) one-month LIBOR plus 1%. The agreement contains provisions related to the determination of successor rates to address the possible phase-out or unavailability of designated reference rates. As of December 31, 2020 and 2019, no amounts were outstanding under this facility.

It is anticipated that LIBOR will be phased out and replaced by 2023. While various replacement reference rates have been discussed, an alternative reference rate to LIBOR has not yet been widely adopted. Therefore, the mechanics to modify existing contracts that reference LIBOR have not been finalized. We are currently evaluating the impact that the change in the reference rate will have on our financial condition. See Part I, Item 1A. Risk Factors —*Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.*

In February 2020, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2023.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant that requires us to maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2020.

See Part IV—Note 15, Financing arrangements, and Note 18, Derivative instruments, to the Consolidated Financial Statements.

Cash flows

Our summarized cash flow activity was as follows (in millions):

	Years ended December 31,		
	2020	2019	2018
Net cash provided by operating activities	$ 10,497	$ 9,150	$ 11,296
Net cash (used in) provided by investing activities	$ (5,401)	$ 5,709	$ 14,339
Net cash used in financing activities	$ (4,867)	$ (15,767)	$ (22,490)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities increased during 2020 primarily due to higher Net income after adding back the noncash amortization related to the acquisition of Otezla®, the monetization of interest rate swap contracts and working capital adjustments. Cash provided by operating activities decreased during 2019 primarily due to changes in working capital, an increase in payments to the IRS related to an advance deposit and lower Net income.

Investing

Cash used in investing activities during 2020 was primarily due to our $3.2 billion of purchases of equity method investments, primarily BeiGene, and net cash outflows related to marketable securities of $1.5 billion. Cash provided by investing activities during 2019 and 2018 was primarily due to net cash inflows related to marketable securities of $20.0 billion and $15.0 billion, respectively. The liquidation of portions of our marketable securities portfolio in 2019 was primarily the result of funding the acquisition of Otezla® and our investment in BeiGene and, in 2018, to fund our tender offer to repurchase our common stock. Capital expenditures were $608 million, $618 million and $738 million in 2020, 2019 and 2018, respectively. We currently estimate 2021 spending on capital projects to be approximately $900 million. A majority of the increase in expenditures relates to expansion of manufacturing capacity to enable supply of products and product candidates.

Financing

Cash used in financing activities during 2020 was primarily due to repayments of debt of $6.5 billion, the payment of dividends of $3.8 billion and payments to repurchase our common stock of $3.5 billion, partially offset by proceeds from issuance of debt of $8.9 billion. Cash used in financing activities during 2019 was primarily due to repurchases of our common stock of $7.7 billion, repayments of debt of $4.5 billion and payments of dividends of $3.5 billion. Cash used in financing activities during 2018 was primarily due to repurchases of common stock of $17.8 billion, payments of dividends of $3.5 billion and repayments of debt of $1.1 billion.

See Part IV—Note 9, Investments, Note 15, Financing arrangements, and Note 16, Stockholders' equity, to the Consolidated Financial Statements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are material or reasonably likely to become material to our consolidated financial position or consolidated results of operations.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent liabilities for which we cannot reasonably predict future payment. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information. Timing of payments and actual amounts paid may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations.

The following table represents our contractual obligations aggregated by type (in millions):

	Payments due by period as of December 31, 2020				
Contractual obligations	**Total**	**Year 1**	**Years 2 and 3**	**Years 4 and 5**	**Years 6 and beyond**
Long-term debt obligations[1][2]	$ 54,293	$ 1,207	$ 7,857	$ 4,944	$ 40,285
Operating lease obligations[3]	864	166	268	102	328
Purchase obligations[4]	2,697	2,129	375	121	72
U.S. repatriation tax[5]	5,575	587	1,687	3,301	—
Unrecognized tax benefits (UTBs)[6]	—	—	—	—	—
Total contractual obligations	$ 63,429	$ 4,089	$ 10,187	$ 8,468	$ 40,685

(1) Long-term debt obligations includes future interest payments on our fixed-rate obligations at the contractual coupon rates. To achieve a desired mix of fixed-rate and floating-rate debt, we enter into interest rate swap contracts that effectively convert a fixed-rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the terms of the related hedge contracts. We used an interest rate forward curve as of December 31, 2020, in computing net amounts to be paid or received under our interest rate swap contracts, which resulted in an aggregate net decrease in future interest payments of $67 million. See Part IV—Note 15, Financing arrangements, to the Consolidated Financial Statements.

(2) Long-term debt obligations includes contractual interest payments and principal repayments of our foreign-denominated debt obligations. In order to hedge our exposure to foreign currency exchange rate risk associated with our euro-, pound-sterling- and Swiss-franc-denominated long-term debt, we entered into cross-currency swap contracts that effectively converted interest payments and principal repayments on this debt from euros, pounds sterling and Swiss francs to U.S. dollars. For purposes of this table, we used the contracted exchange rates in the cross-currency swap contracts to compute the net amounts of future interest payments and principal repayments on this debt. See Part IV—Note 18, Derivative instruments, to the Consolidated Financial Statements.

(3) Operating lease obligations includes payments for leases that have not yet commenced, net of lease incentives, and excludes $107 million of future receipts under noncancelable subleases of abandoned facilities.

(4) Purchase obligations relates primarily to (i) R&D commitments (including those related to clinical trials) for new and existing products, (ii) capital expenditures and (iii) open purchase orders for the acquisition of goods and services in the ordinary course of business. Our obligation to pay certain of these amounts may be reduced based on certain future events.

(5) Under the 2017 Tax Act, we elected to pay in eight annual installments the repatriation tax related primarily to our prior indefinitely invested earnings of our foreign operations. See Part IV—Note 19, Contingencies and commitments—Commitments–U.S. repatriation tax, to the Consolidated Financial Statements.

(6) Liabilities for UTBs are not included in the table above because due to their nature there is a high degree of uncertainty regarding the timing of future cash outflows and other events that extinguish these liabilities. See Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

In addition to amounts in the table above, we are contractually obligated to pay additional amounts that in the aggregate are significant, upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties, including contingent consideration incurred in the acquisitions of K-A and BioVex Group Inc. (BioVex). These payments are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring. These contingent payments have not been

included in the table above, and except with respect to the fair value of the contingent consideration obligations, are not recorded on our Consolidated Balance Sheets. As of December 31, 2020, the maximum amount that may be payable in the future for agreements we have entered into with third parties is $5.4 billion, including $250 million of contingent consideration payments in connection with the acquisition of BioVex.

Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate. Accruals are also adjusted to reflect actual results. Amounts recorded in Accrued liabilities in the Consolidated Balance Sheets for sales deductions were as follows (in millions):

	Rebates	Chargebacks	Other deductions	Total
Balance as of December 31, 2017	$ 1,867	$ 272	$ 108	$ 2,247
Amounts charged against product sales	6,180	6,926	1,180	14,286
Payments	(5,458)	(6,744)	(1,161)	(13,363)
Balance as of December 31, 2018	2,589	454	127	3,170
Amounts charged against product sales	6,825	7,090	1,292	15,207
Payments	(6,249)	(6,985)	(1,263)	(14,497)
Balance as of December 31, 2019	3,165	559	156	3,880
Amounts charged against product sales	9,167	8,223	1,818	19,208
Payments	(8,353)	(8,191)	(1,735)	(18,279)
Balance as of December 31, 2020	$ 3,979	$ 591	$ 239	$ 4,809

For the years ended December 31, 2020, 2019 and 2018, total sales deductions were 44%, 41% and 39% of gross product sales, respectively. The increase in the total sales deductions balance as of December 31, 2020, compared to December 31, 2019, was primarily driven by the increase in gross sales and the impact of higher U.S. commercial rebate rates. Included in the amounts are immaterial net adjustments related to prior-year sales due to changes in estimates. Such amounts represent less than 1% of the aggregate sales deductions charged against product sales in the years ended December 31, 2020, 2019 and 2018.

In the United States, we utilize wholesalers as the principal means of distributing our products to healthcare providers such as physicians or their clinics, dialysis centers, hospitals and pharmacies. Products we sell in Europe are distributed principally to hospitals and/or wholesalers depending on the distribution practice in each country where the products are sold. We monitor the inventory levels of our products at our wholesalers by using data from our wholesalers and other third parties, and we believe wholesaler inventories have been maintained at appropriate levels (generally two to three weeks) given end-user demand. Accordingly, historical fluctuations in wholesaler inventory levels have not significantly affected our method of estimating sales deductions and returns.

Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given year, can be affected by the mix of products sold.

Rebates include primarily amounts paid to payers and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements that vary by product, by payer and by individual payer plans. As we sell products, we estimate the amount of rebate we will pay based on the product sold, contractual terms, estimated patient population, historical experience and wholesaler inventory levels; and we accrue these rebates in the period the related sales are recorded. We then adjust the rebate accruals as

more information becomes available and to reflect actual claims experience. Estimating such rebates is complicated, in part because of the time delay between the date of sale and the actual settlement of the liability. We believe the methodology we use to accrue for rebates is reasonable and appropriate given current facts and circumstances, but actual results may differ.

Wholesaler chargebacks relate to our contractual agreements to sell products to healthcare providers in the United States at fixed prices that are lower than the prices we charge wholesalers. When healthcare providers purchase our products through wholesalers at these reduced prices, wholesalers charge us for the difference between their purchase prices and the contractual prices between Amgen and the healthcare providers. The provision for chargebacks is based on the expected sales by our wholesaler customers to healthcare providers. Accruals for wholesaler chargebacks are less difficult to estimate than rebates are, and they closely approximate actual results because chargeback amounts are fixed at the date of purchase by the healthcare providers and because we generally settle the liability for these deductions within a few weeks.

Product returns

Returns are estimated by comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. In each of the past three years, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-year sales return provisions have historically been immaterial.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is measured based on the largest benefit that is more likely than not to be realized. The amount of UTBs is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by tax authorities, new information obtained during a tax examination or resolution of an examination. We believe our estimates for uncertain tax positions are appropriate and sufficient for any assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense.

Certain items are included in our tax return at different times than they are reflected in the financial statements, and they cause temporary differences between the tax bases of assets and liabilities and their reported amounts. Such temporary differences create deferred tax assets and liabilities. Deferred tax assets are generally items that can be used as a tax deduction or credit in the tax return in future years but for which we have already recorded the tax benefit in the consolidated financial statements. We establish valuation allowances against our deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities are either (i) tax expenses recognized in the consolidated financial statements for which payment has been deferred, (ii) expenses for which we have already taken a deduction on the tax return but have not yet recognized in the consolidated financial statements or (iii) liabilities for the difference between the book basis and tax basis of the intangible assets acquired in many business combinations, as future expenses associated with these assets most often will not be tax deductible.

We are a vertically integrated enterprise with operations in the United States and various foreign jurisdictions. We are subject to income tax in the jurisdictions where we conduct operations based on the tax laws and principles of such jurisdictions and the functions, risks and activities performed therein. Our pretax income is therefore attributed to domestic or foreign sources based on the operations performed and risks assumed in each location and the tax laws and principles of the respective taxing jurisdictions. For example, we conduct significant operations in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes, pertaining to manufacturing, distribution and other related functions to meet our worldwide product demand. Income from our operations in Puerto Rico is subject to tax incentive grants through 2035.

As previously disclosed, in 2017 we received an RAR and a modified RAR from the IRS for the years 2010, 2011 and 2012 proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. However, we have been unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a Notice of Deficiency which we would expect to vigorously contest through the judicial process. In addition, in 2020 we

received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagree with the 2013, 2014 and 2015 proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. The IRS audit for years 2016, 2017 and 2018 is expected to start in the near term. We are also currently under examination by a number of other state and foreign tax jurisdictions. Final resolution of these complex matters is not likely within the next 12 months. We believe our accrual for income tax liabilities is appropriate based

on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our consolidated financial statements. See Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

Our operations are subject to the tax laws, regulations and administrative practices of the United States, the U.S. territory of Puerto Rico, U.S. state jurisdictions and other countries in which we do business. Significant changes in these rules could have a material adverse effect on our results of operations. See Part I, Item 1A. Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability*.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters such as intellectual property disputes, contractual disputes and class action suits that are complex in nature and have outcomes that are difficult to predict. We describe our legal proceedings and other matters that are significant or that we believe could become significant in Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Valuation of assets and liabilities in connection with acquisitions

We have acquired and continue to acquire intangible assets in connection with business combinations and asset acquisitions. These intangible assets consist primarily of technology associated with currently marketed human therapeutic products and IPR&D product candidates. Discounted cash flow models are typically used to determine the fair values of these intangible assets for purposes of allocating consideration paid to the net assets acquired in an acquisition. See Part IV—Note 2, Acquisitions, to the Consolidated Financial Statements. These models require the use of significant estimates and assumptions, including but not limited to:

- determining the timing and expected costs to complete in-process projects, taking into account the stage of completion at the acquisition date;
- projecting the probability and timing of obtaining marketing approval from the FDA and other regulatory agencies for product candidates;
- estimating the timing of and future net cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates to calculate the present values of the cash flows.

We believe the fair values used to record intangible assets acquired in connection with business combinations and asset acquisitions are based on reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Impairment of long-lived assets

We review the carrying value of our property, plant and equipment and our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows to be generated by the long-lived asset is compared to the carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value.

We believe our estimations of future cash flows used for assessing impairment of long-lived assets are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

Impairment of equity method investments

We review the carrying value of our equity method investments whenever events or changes in circumstances indicate that the carrying amount of an investment may not be recoverable. We record impairment losses on our equity method investments if we deem the impairment to be other-than-temporary. We deem an impairment to be other-than-temporary based on various factors, including but not limited to, the length of time and the extent to which the fair value is below the carrying value, volatility of the security price, the financial condition of the issuer, changes in technology that may impair the earnings potential of the investment and our intent and ability to retain the investment to allow for a recovery in fair value.

We believe our judgments used in assessing impairment of equity method investments are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

Recently Issued Accounting Standards

See Part IV—Note 1, Summary of significant accounting policies, to the Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 31, 2020.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks that may result from changes in interest rates, foreign currency exchange rates and prices of equity instruments as well as changes in general economic conditions in the countries where we conduct business. To reduce certain of these risks, we enter into various types of foreign currency and interest rate derivative hedging transactions as part of our risk management program. We do not use derivatives for speculative trading purposes.

In the discussion that follows, we have assumed a hypothetical change in interest rates of 100 basis points from those as of December 31, 2020 and 2019. Except as noted below, we have also assumed a hypothetical 20% change in foreign currency exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2020 and 2019.

Interest-rate-sensitive financial instruments

Our portfolio of available-for-sale investments as of December 31, 2020 and 2019, was composed of U.S. Treasury securities and money market mutual funds, and with respect to investments as of December 31, 2019, corporate debt securities and other short-term interest-bearing securities. The fair values of our available-for-sale investments were $9.8 billion and $8.2 billion as of December 31, 2020 and 2019, respectively. Duration is a sensitivity measure that can be used to approximate the change in the value of a security that will result from a 100 basis point change in interest rates. Applying a duration model, a hypothetical 100 basis point increase in interest rates as of December 31, 2020 and 2019, would not have resulted in a material reduction in the fair values of these securities. In addition, a hypothetical 100 basis point decrease in interest rates as of December 31, 2020 and 2019, would not result in a material effect on income in the respective ensuing year.

As of December 31, 2020, we had outstanding debt with a carrying value of $33.0 billion and a fair value of $39.4 billion. As of December 31, 2019, we had outstanding debt with a carrying value of $29.9 billion and a fair value of $33.7 billion. Our outstanding debt was composed almost entirely of debt with fixed interest rates. Changes in interest rates do not affect interest expense on fixed-rate debt. Changes in interest rates would, however, affect the fair values of fixed-rate debt. A hypothetical 100 basis point decrease in interest rates relative to interest rates as of December 31, 2020 and 2019, would have resulted in increases of $4.5 billion and $3.0 billion, respectively, in the aggregate fair value of our outstanding debt on each of these dates. Analysis of the debt does not consider the impact that hypothetical changes in interest rates would have on the related interest rate swap contracts and cross-currency swap contracts, discussed below.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified and were designated for accounting purposes as fair value hedges for certain of our fixed-rate debt. These

interest rate swap contracts effectively converted a fixed-rate interest coupon to a floating-rate LIBOR-based coupon over the life of the respective notes. Interest rate swap contracts with aggregate notional amounts of $5.9 billion and $9.6 billion were outstanding as of December 31, 2020 and 2019, respectively. A hypothetical 100 basis point increase in interest rates relative to interest rates as of December 31, 2020 and 2019, would have resulted in reductions in fair values of approximately $230 million and $380 million, respectively, on our interest rate swap contracts on these dates. Analysis of the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair values of debt that these interest-rate-sensitive instruments were designed to offset.

As of December 31, 2020 and 2019, we had outstanding cross-currency swap contracts with aggregate notional amounts of $4.8 billion that hedge our foreign-currency-denominated debt and related interest payments. These contracts effectively convert interest payments and principal repayment of this debt to U.S. dollars from euros, pounds sterling and Swiss francs and are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates as of December 31, 2020 and 2019, would have resulted in reductions in the fair values of our cross-currency swap contracts of approximately $250 million and $280 million, respectively.

Foreign-currency-sensitive financial instruments

Our international operations are affected by fluctuations in the value of the U.S. dollar as compared to foreign currencies, predominantly the euro. Increases and decreases in our international product sales from movements in foreign currency exchange rates are partially offset by the corresponding increases or decreases in our international operating expenses. Increases and decreases in our foreign-currency-denominated assets from movements in foreign currency exchange rates are partially offset by the corresponding increases or decreases in our foreign-currency-denominated liabilities. To further reduce our net exposure to foreign currency exchange rate fluctuations on our results of operations, we enter into foreign currency forward, option and cross-currency swap contracts.

As of December 31, 2020, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and a fair value of $4.8 billion and $5.4 billion, respectively. As of December 31, 2019, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and a fair value of $4.5 billion and $5.0 billion, respectively. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2020, would have resulted in an increase in fair value of this debt of $1.1 billion on this date and a reduction in income in the ensuing year of $1.0 billion. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2019, would have resulted in an increase in fair value of this debt of $1.0 billion on this date and a reduction in income in the ensuing year of $900 million. The impact on income from these hypothetical changes in foreign currency exchange rates would be substantially offset by the impact such changes would have on related cross-currency swap contracts, which are in place for the related foreign-currency-denominated debt.

We have cross-currency swap contracts that are designated as cash flow hedges of our debt denominated in euros, pounds sterling and Swiss francs with aggregate notional amounts of $4.8 billion as of both December 31, 2020 and 2019. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would have resulted in reductions in the fair values of these contracts of $1.1 billion and $1.0 billion on these dates, respectively. The impact of this hypothetical adverse movement in foreign currency exchange rates on ensuing years' income from these contracts would be fully offset by the corresponding hypothetical changes in the carrying amounts of the related hedged debt.

We enter into foreign currency forward and options contracts that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2020, the fair values of these contracts were a $28 million asset and a $237 million liability. As of December 31, 2019, the fair values of these contracts were a $223 million asset and a $31 million liability. As of December 31, 2020, we had primarily euro based open foreign currency forward contracts with notional amounts of $5.1 billion. As of December 31, 2019, we had primarily euro based open foreign currency forward contracts with notional amounts of $5.0 billion. With regard to foreign currency forward and option contracts that were open as of December 31, 2020, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2020, would have resulted in a reduction in fair value of these contracts of approximately $1.1 billion on this date and in the ensuing year, a reduction in income of approximately $420 million. With regard to contracts that were open as of December 31, 2019, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2019, would have resulted in a reduction in fair value of these contracts of $930 million on this date and in the ensuing year, a reduction in income of $400 million. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign-currency-sensitive instruments were designed to offset.

As of December 31, 2020 and 2019, we had open short-duration foreign currency forward contracts that mature in less than one month, with notional amounts of $1.0 billion and $1.2 billion, respectively, that hedged fluctuations of certain assets and liabilities denominated in foreign currencies but were not designated as hedges for accounting purposes. These contracts had no material net unrealized gains or losses as of December 31, 2020 and 2019. With

regard to these foreign currency forward contracts that were open as of December 31, 2020 and 2019, a hypothetical 5% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would not have a material effect on the fair values of these contracts or related income in the respective ensuing years. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on assets and liabilities that these foreign-currency-sensitive instruments were designed to offset.

Market-price-sensitive financial instruments

As of December 31, 2020 and 2019, we were exposed to price risk on equity securities included in our portfolio of investments, which were acquired primarily for the promotion of business and strategic objectives. These investments are generally in small-capitalization stocks in the biotechnology industry. Price risk relative to our equity investment portfolio as of December 31, 2020 and 2019, was not material.

Counterparty credit risks

Our financial instruments, including derivatives, are subject to counterparty credit risk, which we consider as part of the overall fair value measurement. Our financial risk management policy limits derivative transactions by requiring that transactions be made only with institutions with minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch; and it places exposure limits on the amount with any individual counterparty. In addition, we have an investment policy that limits investments to certain types of debt and money market instruments issued by institutions with investment-grade credit ratings and places restriction on maturities and concentrations by asset class and issuer.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is incorporated herein by reference to the financial statements and schedule listed in Item 15(a)1 and (a)2 of Part IV and included in this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under the Securities Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, Amgen's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2020.

Management determined that as of December 31, 2020, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP in the United States. However, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and reporting.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our assessment, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

The effectiveness of the Company's internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing below, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2020.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Amgen Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Amgen Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Amgen Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 and our report dated February 8, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Los Angeles, California
February 8, 2021

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about our Directors is incorporated by reference from the section entitled ITEM 1—ELECTION OF DIRECTORS in our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2020 (the Proxy Statement). Information about the procedures by which stockholders may recommend nominees for the Board of Directors is incorporated by reference from APPENDIX A —AMGEN INC. BOARD OF DIRECTORS GUIDELINES FOR DIRECTOR QUALIFICATIONS AND EVALUATIONS and OTHER MATTERS—Stockholder Proposals for the 2022 Annual Meeting in our Proxy Statement. Information about our Audit Committee, members of the committee and our Audit Committee financial experts is incorporated by reference from the section entitled CORPORATE GOVERNANCE—Audit Committee in our Proxy Statement. Information about our executive officers is contained in the discussion entitled Part I—Item 1. Business—Information about our Executive Officers.

Code of Ethics

We maintain a Code of Ethics for the Chief Executive Officer and Senior Financial Officers applicable to our principal executive officer, principal financial officer, principal accounting officer or controller and other persons performing similar functions. To view this code of ethics free of charge, please visit our website at www.amgen.com. (This website address is not intended to function as a hyperlink, and the information contained in our website is not intended to be a part of this filing.) We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to or a waiver from a provision of this code of ethics, if any, by posting such information on our website as set forth above.

Item 11. EXECUTIVE COMPENSATION

Information about director and executive compensation is incorporated by reference from the section entitled EXECUTIVE COMPENSATION in our Proxy Statement. Information about compensation committee matters is incorporated by reference from the sections entitled CORPORATE GOVERNANCE—Compensation and Management Development Committee and CORPORATE GOVERNANCE—Compensation Committee Report in our Proxy Statement.

Item 12. **SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table sets forth certain information as of December 31, 2020, concerning the shares of our common stock that may be issued under any form of award granted under our equity compensation plans in effect as of December 31, 2020 (including upon the exercise of options, upon the vesting of awards of restricted stock units (RSUs) or when performance units are earned and related dividend equivalents have been granted).

	(a)	(b)	(c)
Plan category	**Number of securities to be issued upon exercise of outstanding options and rights**	**Weighted-average exercise price of outstanding options and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**
Equity compensation plans approved by Amgen security holders:			
Amended and Restated 2009 Equity Incentive Plan[1]	9,890,702	$ 179.92	23,108,576
Amended and Restated 1991 Equity Incentive Plan[2]	5,913	—	—
Amended and Restated Employee Stock Purchase Plan	—	—	4,393,614
Total approved plans	9,896,615	179.92	27,502,190
Equity compensation plan not approved by Amgen security holders:			
Amgen Profit Sharing Plan for Employees in Ireland[3]	—	—	60,059
Total unapproved plans	—	—	60,059
Total all plans	9,896,615	$ 179.92	27,562,249

(1) The Amended and Restated 2009 Equity Incentive Plan employs a fungible share-counting formula for determining the number of shares available for issuance under the plan. In accordance with this formula, each option or stock appreciation right counts as one share, while each RSU, performance unit or dividend equivalent counts as 1.9 shares. The number under column (a) represents the actual number of shares issuable under our outstanding awards without giving effect to the fungible share-counting formula. The number under column (c) represents the number of shares available for issuance under this plan based on each such available share counting as one share. Commencing with the grants made in April 2012, RSUs and performance units accrue dividend equivalents that are payable in shares only to the extent and when the underlying RSUs vest or underlying performance units have been earned and the related shares are issued to the grantee. The performance units granted under this plan are earned based on the accomplishment of specified performance goals at the end of their respective three-year performance periods; the number of performance units granted represent target performance, and the maximum number of units that could be earned based on our performance is 200% of the performance units granted in 2018, 2019 and 2020.

As of December 31, 2020, the number of outstanding awards under column (a) includes (i) 4,721,305 shares issuable upon the exercise of outstanding options with a weighted-average exercise price of $179.92; (ii) 3,256,390 shares issuable upon the vesting of outstanding RSUs (including 199,676 related dividend equivalents); and (iii) 1,913,007 shares subject to outstanding 2018, 2019 and 2020 performance units (including 93,738 related dividend equivalents). The weighted-average exercise price shown in column (b) is for the outstanding options only. The number of available shares under column (c) represents the number of shares that remain available for future issuance under this plan as of December 31, 2020, employing the fungible share formula and presumes the issuance of target shares under the performance units granted in 2018, 2019 and 2020 and related dividend equivalents. The numbers under columns (a) and (c) do not give effect to the additional shares that could be issuable in the event above target performance on the performance goals

under these outstanding performance units is achieved. Maximum performance under these goals could result in 200% of target shares being awarded for performance units granted in 2018, 2019 and 2020.

(2) This plan has terminated as to future grants. The number under column (a) with respect to this plan includes 5,913 shares issuable upon the settlement of deferred RSUs (including 1,160 related dividend equivalents).

(3) The Amgen Profit Sharing Plan for Employees in Ireland (the Profit Sharing Plan) was approved by the Board of Directors on July 28, 2011. The Profit Sharing Plan permits eligible employees of the Company's subsidiaries located in Ireland who participate in the Profit Sharing Plan to apply a portion of their qualifying bonus and salary to the purchase of the Company's common stock on the open market at the market price by a third-party trustee as described in the Profit Sharing Plan.

Security Ownership of Directors and Executive Officers and Certain Beneficial Owners

Information about security ownership of certain beneficial owners and management is incorporated by reference from the sections entitled SECURITY OWNERSHIP OF DIRECTORS AND EXECUTIVE OFFICERS and SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS in our Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information about certain relationships and related transactions and director independence is incorporated by reference from the sections entitled CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS and CORPORATE GOVERNANCE—Director Independence in our Proxy Statement.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information about the fees for professional services rendered by our independent registered public accountants is incorporated by reference from the section entitled AUDIT MATTERS—Independent Registered Public Accountants in our Proxy Statement.

PART IV

Item 15. **EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

(a)1. Index to Financial Statements

The following Consolidated Financial Statements are included herein:

	Page number
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Statements of Income for each of the three years in the period ended December 31, 2020	F-4
Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2020	F-5
Consolidated Balance Sheets as of December 31, 2020 and 2019	F-6
Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2020	F-7
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2020	F-8
Notes to Consolidated Financial Statements	F-9

(a)2. Index to Financial Statement Schedules

The following Schedule is filed as part of this Annual Report on Form 10-K:

	Page number
II. Valuation and Qualifying Accounts	F-60

All other schedules are omitted because they are not applicable, not required or because the required information is included in the consolidated financial statements or notes thereto.

(a)3. Exhibits

Exhibit No.	Description
2.1	Asset Purchase Agreement, dated August 25, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.2	Amendment No. 1 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on October 17, 2019 and incorporated herein by reference.)
2.3	Amendment No. 2 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.4	Letter Agreement, dated November 21, 2019, by and between Amgen Inc. and the parties named therein re: Treatment of Certain Product Inventory in connection with Amgen's acquisition of Otezla® (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.5	Irrevocable Guarantee, dated August 25, 2019, by and between Amgen Inc. and Bristol-Myers Squibb Company. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)

4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.6	Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.7	Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.8	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.9	Officers' Certificate of Amgen Inc., dated May 30, 2007, including form of the Company's 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
4.10	Officers' Certificate of Amgen Inc., dated May 23, 2008, including form of the Company's 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)
4.11	Officers' Certificate of Amgen Inc., dated January 16, 2009, including form of the Company's 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)
4.12	Officers' Certificate of Amgen Inc., dated March 12, 2010, including form of the Company's 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.)
4.13	Officers' Certificate of Amgen Inc., dated September 16, 2010, including form of the Company's 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)
4.14	Officers' Certificate of Amgen Inc., dated June 30, 2011, including form of the Company's 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)
4.15	Officers' Certificate of Amgen Inc., dated November 10, 2011, including form of the Company's 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)
4.16	Officers' Certificate of Amgen Inc., dated December 5, 2011, including form of the Company's 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)
4.17	Officers' Certificate of Amgen Inc., dated May 15, 2012, including forms of the Company's 3.625% Senior Notes due 2022 and 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)
4.18	Officers' Certificate of Amgen Inc., dated September 13, 2012, including form of the Company's 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)
4.19	Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
4.20	Officers' Certificate of Amgen Inc., dated May 22, 2014, including form of the Company's 3.625% Senior Notes due 2024. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)

4.21	Officer's Certificate of Amgen Inc., dated May 1, 2015, including forms of the Company's 2.700% Senior Notes due 2022, 3.125% Senior Notes due 2025 and 4.400% Senior Notes due 2045. (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.)
4.22	Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including forms of the Company's 1.250% Senior Notes due 2022 and 2.000% Senior Notes due 2026. (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.)
4.23	Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.24	Terms of the Bonds for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.25	Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.26	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of May 11, 2017 including form of the Company's 2.650% Senior Notes due 2022. (Filed as an exhibit to Form 8-K on May 11, 2017 and incorporated herein by reference.)
4.28	Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated by reference.)
4.29	Officer's Certificate of Amgen Inc., dated as of February 21, 2020, including forms of the Company's 1.900% Senior Notes due 2025, 2.200% Senior Notes due 2027, 2.450% Senior Notes due 2030, 3.150% Senior Notes due 2040 and 3.375% Senior Notes due 2050. (Filed as an exhibit to Form 8-K on February 21, 2020 and incorporated herein by reference.)
4.30	Officer's Certificate of Amgen Inc., dated as of May 6, 2020, including form of the Company's 2.300% Senior Notes due 2031. (Filed as an exhibit to Form 8-K on May 6, 2020 and incorporated herein by reference.)
4.31	Officer's Certificate of Amgen Inc., dated as of August 17, 2020, including forms of the Company's 2.770% Senior Notes due 2053. (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)
4.32	Registration Rights Agreement, dated as of August 17, 2020, by and among Amgen Inc., BofA Securities, Inc. and J.P. Morgan Securities LLC, as lead dealer managers, and BNP Paribas Securities Corp., Deutsche Bank Securities Inc., RBC Capital Markets, LLC, Blaylock Van, LLC and Siebert Williams Shank & Co., LLC, as co-dealer managers (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)
4.33*	Description of Amgen Inc.'s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1+	Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
10.2+	First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.)
10.3+	Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)
10.4+*	Form of Grant of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 15, 2020.)
10.5+*	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 15, 2020.)

10.6+	Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.7+*	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on December 15, 2020.)
10.8+*	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended and Restated on October 21, 2020.)
10.9+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.10+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.11+	Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.12+	Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.13+	First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.14+	Second Amendment to the Amgen Inc. Supplemental Retirement Plan (As Amended and Restated effective October 23, 2019). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.15+	Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.)
10.16+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.17+	First Amendment to the Amgen Inc. Executive Incentive Plan, effective December 13, 2012. (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.)
10.18+	Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.19+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.20+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.21+	Second Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2020). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.22+	Agreement between Amgen Inc. and Murdo Gordon, dated July 25, 2018. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2018 on October 31, 2018 and incorporated herein by reference.)
10.23+	Agreement between Amgen Inc. and Peter Griffith, dated October 18, 2019. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)

10.24 Second Amended and Restated Credit Agreement, dated December 12, 2019, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent. (Filed as an exhibit to Form 8-K on December 12, 2019 and incorporated herein by reference.)

10.25 Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)

10.26 Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)

10.27 Letter Agreement, dated June 25, 2019, by and between Amgen Inc. and UCB Celltech (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2019 on July 31, 2019 and incorporated herein by reference.)

10.28 Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)

10.29 Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)

10.30 Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)

10.31 Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)

10.32 Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)

10.33 Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)

10.34 Side Letter Regarding Collaboration Agreement and Stivarga Agreement, dated February 13, 2020, by and between Onyx Pharmaceuticals, Inc. and Bayer HealthCare LLC. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)

10.35 Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)

10.36 Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

10.37 Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

10.38 Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

10.39	Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.40	Amendment No. 1 to the Collaboration Agreement, dated March 20, 2018, by and between Novartis Pharma AG and Amgen Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.)
10.41	Amendment No. 2 to the Collaboration Agreement, dated August 19, 2020, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2020 on October 29, 2020 and incorporated herein by reference.)
10.42	Collaboration Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene Switzerland GmbH, a wholly-owned subsidiary of BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.43	Guarantee, dated as of October 31, 2019, made by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.44	Share Purchase Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.45	Amendment No. 1 to Share Purchase Agreement, dated December 6, 2019, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.46	Restated Amendment No. 2 to Share Purchase Agreement, dated September 24, 2020, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2020 on October 29, 2020 and incorporated herein by reference.)
10.47	Collaboration Agreement dated March 30, 2012 by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, a wholly owned subsidiary of AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2012 on May 8, 2012 and incorporated herein by reference.)
10.48	Amendment No. 1 to the Collaboration Agreement, dated October 1, 2014, by and among Amgen Inc., AstraZeneca Collaboration Ventures, LLC and AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2014 on February 19, 2015 and incorporated herein by reference.)
10.49	Amendment Nos. 2 through 6 to the March 30, 2012 Collaboration Agreement between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, dated May 2 and 27 and October 2, 2016, January 31, 2018, and May 15, 2020, respectively (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2020 on July 29, 2020 and incorporated herein by reference.)
10.50*	Amendment No. 7 to the Collaboration Agreement, dated December 18, 2020, by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.)
21*	Subsidiaries of the Company.
23	Consent of the Independent Registered Public Accounting Firm. The consent is set forth on page 94 of this Annual Report on the 10-K.
24	Power of Attorney. The Power of Attorney is set forth on page 95 of this Annual Report on Form 10-K.
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.

101.INS	Inline XBRL Instance Document - the instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

(* = filed herewith)
(** = furnished herewith and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended)
(+ = management contract or compensatory plan or arrangement)

Item 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMGEN INC.
(Registrant)

Date: February 8, 2021

By: /s/ PETER H. GRIFFITH

Peter H. Griffith
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-3 No. 333-236351) of Amgen Inc.,
- Registration Statement (Form S-8 No. 333-159377) pertaining to the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan,
- Registration Statement (Form S-8 No. 33-39183) pertaining to the Amgen Inc. Amended and Restated Employee Stock Purchase Plan,
- Registration Statements (Form S-8 No. 33-39104, as amended by Form S-8 Nos. 333-144581 and 333-216719) pertaining to the Amgen Retirement and Savings Plan,
- Registration Statements (Form S-8 Nos. 33-47605, 333-144580 and 333-216715) pertaining to The Retirement and Savings Plan for Amgen Manufacturing, Limited (formerly known as the Retirement and Savings Plan for Amgen Manufacturing, Inc.),
- Registration Statements (Form S-8 Nos. 333-81284, 333-177868 and 333-216723) pertaining to the Amgen Nonqualified Deferred Compensation Plan, and
- Registration Statement (Form S-8 No. 333-176240) pertaining to the Amgen Profit Sharing Plan for Employees in Ireland;

of our reports dated February 8, 2021, with respect to the consolidated financial statements of Amgen Inc. and the effectiveness of internal control over financial reporting of Amgen Inc. included in this Annual Report (Form 10-K) of Amgen Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Los Angeles, California
February 8, 2021

EXHIBIT 24

POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Robert A. Bradway, Peter H. Griffith and Jonathan P. Graham, or any of them, his or her attorney-in-fact, each with the power of substitution and re-substitution, for him or her in any and all capacities, to sign any amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/S/ ROBERT A. BRADWAY **Robert A. Bradway**	Chairman of the Board, Chief Executive Officer and President, and Director (Principal Executive Officer)	2/8/2021
/S/ PETER H. GRIFFITH **Peter H. Griffith**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	2/8/2021
/S/ LINDA H. LOUIE **Linda H. Louie**	Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)	2/8/2021
/S/ WANDA M. AUSTIN **Wanda M. Austin**	Director	2/8/2021
/S/ BRIAN J. DRUKER **Brian J. Druker**	Director	2/8/2021
/S/ ROBERT A. ECKERT **Robert A. Eckert**	Director	2/8/2021
/S/ GREG C. GARLAND **Greg C. Garland**	Director	2/8/2021
/S/ FRED HASSAN **Fred Hassan**	Director	2/8/2021
/S/ CHARLES M. HOLLEY, JR. **Charles M. Holley, Jr.**	Director	2/8/2021
/S/ TYLER JACKS **Tyler Jacks**	Director	2/8/2021
/S/ ELLEN J. KULLMAN **Ellen J. Kullman**	Director	2/8/2021
/S/ AMY E. MILES **Amy E. Miles**	Director	2/8/2021
/S/ RONALD D. SUGAR **Ronald D. Sugar**	Director	2/8/2021
/S/ R. SANDERS WILLIAMS **R. Sanders Williams**	Director	2/8/2021

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Amgen Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amgen Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 8, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Sales deductions

Description of the Matter

As of December 31, 2020, the Company recorded accrued sales deductions of $4.8 billion. As described in Note 1 to the financial statements under the caption "Product sales and sales deductions," revenues from product sales are recognized net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively sales deductions), which are established at the time of sale.

Auditing the estimation of sales deductions, which are netted against product sales, is complex, requires significant judgment, and the amounts involved are material to the financial statements taken as a whole. Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, and is based on an amount that reflects the consideration to which the Company expects to be entitled, which represents an amount that is net of accruals for estimated sales deductions. The estimated sales deductions are based on current contractual and statutory requirements, market events and trends, internal and external historical data, and forecasted customer buying patterns.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the sales deduction processes. This included testing controls over management's review of significant assumptions and inputs used in the estimate of sales deductions, including actual sales, contractual terms, historical experience, wholesaler inventory levels, demand data and estimated patient population. We also tested management's controls over the accuracy of forecasting demand activity as well as the completeness and accuracy of the significant components included in the final sales deduction estimates.

To test management's estimated sales deductions, we obtained management's calculations for the respective estimates and performed the following procedures, among others. We tested management's estimation process over the determination of sales discount accruals by developing an independent expectation of the estimated accrual balances, including comparing accrual balances recorded by management to those implied by historical payment trends, performing a lookback analysis using actual historical data to evaluate the forecasted amounts, assessing subsequent events to determine whether there was any new information that would require adjustment to the initial accruals, evaluating trends in actual sales and discount accrual balances, comparing cash receipts to product sales, confirming terms and conditions for a sample of contracts with the Company's customers, testing a sample of credits issued and payments made throughout the year, and agreeing rates to underlying contract terms.

Unrecognized tax benefits

Description of the Matter

As discussed in Notes 1 and 6 to the consolidated financial statements, the Company operates in various jurisdictions in which differing interpretations of complex tax laws and regulations create uncertainty and necessitate the use of significant judgment in the determination of the Company's unrecognized tax benefits related to allocation of profits among various jurisdictions ("transfer pricing"), particularly in the U.S. federal tax jurisdiction where the Company has significant assets and operations. In this regard, the Company uses significant judgment in (1) determining whether a tax position's technical merits are more-likely-than-not to be sustained and (2) measuring the amount of tax benefit that qualifies for recognition. As of December 31, 2020, the Company accrued $3.4 billion of gross unrecognized tax benefits including transfer pricing. Auditing the assessment of the technical merits and measurement of the Company's unrecognized tax benefits is challenging because they can be complex, highly judgmental, and based on interpretations of tax laws and regulations and application of those interpretations to the Company's facts and circumstances.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the Company's process to assess the technical merits of its tax positions, as well as management's process to measure the unrecognized tax benefits of those tax positions, particularly in regard to transfer pricing. This included testing controls over management's review of the inputs, calculations, assumptions and methods selected to measure the amount of tax benefits that qualify for recognition.

We involved tax and transfer pricing professionals to assist in assessing the technical merits and measurement of certain of the Company's unrecognized tax benefits. Depending on the nature of the specific tax position and, as applicable, developments with the relevant tax authorities, our procedures included obtaining and reviewing the Company's correspondence with such tax authorities and evaluating certain third-party advice to support the Company's evaluations and recorded positions. We used our knowledge of and experience with how the income tax laws and regulations related to transfer pricing are applied by the relevant tax authorities to evaluate the Company's accounting for its unrecognized tax benefits. We evaluated developments in the applicable regulatory environments to assess potential effects on the Company's recorded positions. We analyzed the assumptions and data used by the Company when it determined the amount of tax benefits to recognize, including applicable interest and penalties, and we tested the accuracy of those underlying calculations. We have also evaluated the Company's income tax disclosures included in Note 6 in relation to these matters.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1980.
Los Angeles, California
February 8, 2021

AMGEN INC.

CONSOLIDATED STATEMENTS OF INCOME

Years ended December 31, 2020, 2019 and 2018

(In millions, except per-share data)

	2020	2019	2018
Revenues:			
Product sales	$ 24,240	$ 22,204	$ 22,533
Other revenues	1,184	1,158	1,214
Total revenues	25,424	23,362	23,747
Operating expenses:			
Cost of sales	6,159	4,356	4,101
Research and development	4,207	4,116	3,737
Selling, general and administrative	5,730	5,150	5,332
Other	189	66	314
Total operating expenses	16,285	13,688	13,484
Operating income	9,139	9,674	10,263
Interest expense, net	1,262	1,289	1,392
Interest and other income, net	256	753	674
Income before income taxes	8,133	9,138	9,545
Provision for income taxes	869	1,296	1,151
Net income	$ 7,264	$ 7,842	$ 8,394
Earnings per share:			
Basic	$ 12.40	$ 12.96	$ 12.70
Diluted	$ 12.31	$ 12.88	$ 12.62
Shares used in the calculation of earnings per share:			
Basic	586	605	661
Diluted	590	609	665

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Years ended December 31, 2020, 2019 and 2018

(In millions)

	2020	2019	2018
Net income	$ 7,264	$ 7,842	$ 8,394
Other comprehensive (loss) income, net of reclassification adjustments and taxes:			
Gains (losses) on foreign currency translation	9	(48)	(141)
(Losses) gains on cash flow hedges	(438)	(66)	247
(Losses) gains on available-for-sale securities	(21)	360	(185)
Other losses	(7)	(5)	(2)
Other comprehensive (loss) income, net of taxes	(457)	241	(81)
Comprehensive income	$ 6,807	$ 8,083	$ 8,313

See accompanying notes.

AMGEN INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2020 and 2019

(In millions, except per-share data)

	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,266	$ 6,037
Marketable securities	4,381	2,874
Trade receivables, net	4,525	4,057
Inventories	3,893	3,584
Other current assets	2,079	1,888
Total current assets	21,144	18,440
Property, plant and equipment, net	4,889	4,928
Intangible assets, net	16,587	19,413
Goodwill	14,689	14,703
Other assets	5,639	2,223
Total assets	$ 62,948	$ 59,707
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,421	$ 1,371
Accrued liabilities	10,141	8,511
Current portion of long-term debt	91	2,953
Total current liabilities	11,653	12,835
Long-term debt	32,895	26,950
Long-term tax liabilities	6,968	8,037
Other noncurrent liabilities	2,023	2,212
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value per share; 2,750.0 shares authorized; outstanding— 578.3 shares in 2020 and 591.4 shares in 2019	31,802	31,531
Accumulated deficit	(21,408)	(21,330)
Accumulated other comprehensive loss	(985)	(528)
Total stockholders' equity	9,409	9,673
Total liabilities and stockholders' equity	$ 62,948	$ 59,707

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended December 31, 2020, 2019 and 2018

(In millions, except per-share data)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total
Balance as of December 31, 2017	722.2	$ 30,992	$ (5,072)	$ (679)	$ 25,241
Cumulative effect of changes in accounting principles, net of taxes	—	—	38	(9)	29
Net income	—	—	8,394	—	8,394
Other comprehensive loss, net of taxes	—	—	—	(81)	(81)
Dividends declared on common stock ($5.41 per share)	—	—	(3,482)	—	(3,482)
Issuance of common stock in connection with the Company's equity award programs	1.9	56	—	—	56
Stock-based compensation expense	—	327	—	—	327
Tax impact related to employee stock-based compensation expense	—	(129)	—	—	(129)
Repurchases of common stock	(94.5)	—	(17,855)	—	(17,855)
Balance as of December 31, 2018	629.6	31,246	(17,977)	(769)	12,500
Net income	—	—	7,842	—	7,842
Other comprehensive income, net of taxes	—	—	—	241	241
Dividends declared on common stock ($5.95 per share)	—	—	(3,555)	—	(3,555)
Issuance of common stock in connection with the Company's equity award programs	2.0	97	—	—	97
Stock-based compensation expense	—	323	—	—	323
Tax impact related to employee stock-based compensation expense	—	(135)	—	—	(135)
Repurchases of common stock	(40.2)	—	(7,640)	—	(7,640)
Balance as of December 31, 2019	591.4	31,531	(21,330)	(528)	9,673
Cumulative effect of changes in accounting principles, net of taxes	—	—	(2)	—	(2)
Net income	—	—	7,264	—	7,264
Other comprehensive loss, net of taxes	—	—	—	(457)	(457)
Dividends declared on common stock ($6.56 per share)	—	—	(3,843)	—	(3,843)
Issuance of common stock in connection with the Company's equity award programs	2.1	91	—	—	91
Stock-based compensation expense	—	349	—	—	349
Tax impact related to employee stock-based compensation expense	—	(169)	—	—	(169)
Repurchases of common stock	(15.2)	—	(3,497)	—	(3,497)
Balance as of December 31, 2020	578.3	$ 31,802	$ (21,408)	$ (985)	$ 9,409

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2020, 2019 and 2018

(In millions)

	2020	2019	2018
Cash flows from operating activities:			
Net income	$ 7,264	$ 7,842	$ 8,394
Depreciation, amortization and other	3,601	2,206	1,946
Stock-based compensation expense	330	308	311
Deferred income taxes	(287)	(289)	(363)
Other items, net	(195)	(186)	386
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	(427)	(504)	(378)
Inventories	(215)	(66)	(3)
Other assets	129	10	35
Accounts payable	45	164	(143)
Accrued income taxes, net	(249)	(585)	(361)
Long-term tax liabilities	(482)	(146)	258
Other liabilities	983	396	1,214
Net cash provided by operating activities	10,497	9,150	11,296
Cash flows from investing activities:			
Purchases of marketable securities	(8,477)	(9,394)	(18,741)
Proceeds from sales of marketable securities	2,597	8,842	28,356
Proceeds from maturities of marketable securities	4,381	20,548	5,412
Purchases of property, plant and equipment	(608)	(618)	(738)
Cash paid for acquisitions, net of cash acquired	—	(13,617)	195
Purchases of equity method investments	(3,219)	(24)	(40)
Other	(75)	(28)	(105)
Net cash (used in) provided by investing activities	(5,401)	5,709	14,339
Cash flows from financing activities:			
Net proceeds from issuance of debt	8,914	—	—
Repayment of debt	(6,450)	(4,514)	(1,121)
Repurchases of common stock	(3,486)	(7,702)	(17,794)
Dividends paid	(3,755)	(3,509)	(3,507)
Other	(90)	(42)	(68)
Net cash used in financing activities	(4,867)	(15,767)	(22,490)
Increase (decrease) in cash and cash equivalents	229	(908)	3,145
Cash and cash equivalents at beginning of year	6,037	6,945	3,800
Cash and cash equivalents at end of year	$ 6,266	$ 6,037	$ 6,945

See accompanying notes.

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2020

1. Summary of significant accounting policies

Business

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. We operate in one business segment: human therapeutics.

Principles of consolidation

The consolidated financial statements include the accounts of Amgen as well as its majority-owned subsidiaries. We do not have any significant interests in any variable interest entities. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Revenues

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that an adjustment is appropriate. Accruals are also adjusted to reflect actual results. Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given period, can be affected by the mix of products sold. Included in sales deductions are immaterial net adjustments related to prior-period sales due to changes in estimates. Historically, such amounts have represented less than 1% of the aggregate sales deductions charged against product sales.

Returns are estimated through comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. Historically, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-period sales return provisions have historically been immaterial.

Our payment terms vary by types and locations of customers and the products or services offered. Payment terms differ by jurisdiction and customer, but payment is generally required in a term ranging from 30 to 120 days from date of shipment or satisfaction of the performance obligation. For certain products or services and certain customer types, we may require payment before products are delivered or services are rendered to customers.

Indirect taxes collected from customers and remitted to government authorities and that are related to sales of the Company's products, primarily in Europe, are excluded from revenues.

As a practical expedient, sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in Selling, general and administrative (SG&A) expense in the Consolidated Statements of Income.

Other revenues

Other revenues consist primarily of royalty income and corporate partner revenues. Royalties from licensees are based on third-party sales of licensed products and are recorded when the related third-party product sale occurs. Royalty income is estimated based on historical and forecasted sales trends. Corporate partner revenues are composed mainly of license fees and milestones earned and our share of commercial profits generated from collaborations. See Arrangements with multiple-performance obligations, discussed below.

Arrangements with multiple-performance obligations

From time to time, we enter into arrangements for the research and development (R&D), manufacture and/or commercialization of products and product candidates. Such arrangements may require us to deliver various rights, services and/or goods, including intellectual property rights/licenses, R&D services, manufacturing services and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to Amgen in the form of nonrefundable, upfront license fees; development and commercial performance milestone payments; royalty payments; and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or by using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods or services is transferred. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. We utilize the sales- and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

Research and development costs

R&D costs are expensed as incurred and primarily include salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems' costs; and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs and cost recoveries associated with third-party R&D arrangements, including upfront fees and milestones paid to third parties in connection with technologies that had not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 8, Collaborations.

Selling, general and administrative costs

SG&A costs are primarily composed of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses; the U.S. healthcare reform federal excise fee on Branded Prescription Pharmaceutical Manufacturers and Importers; and other general and administrative costs. Advertising costs are expensed as incurred and were $962 million, $789 million and $674 million during the years ended December 31, 2020, 2019 and 2018, respectively. SG&A expenses also include costs and cost recoveries associated with marketing and promotion efforts under certain collaborative arrangements. Net payment or reimbursement of SG&A costs is recognized when the obligations are incurred or we become entitled to the cost recovery. See Note 8, Collaborations.

Leases

Adoption of new lease standard

In February 2016, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the accounting and disclosure of leases. This new standard requires that lessees recognize the assets and liabilities that arise from leases on the balance sheet, including leases classified as operating leases, and that they disclose qualitative and quantitative information about leasing arrangements. The FASB subsequently issued additional amendments to address issues arising from the implementation of the new lease standard. We adopted this standard as of January 1, 2019, using the modified-retrospective method, which provides a method for recording existing leases at adoption. We used the adoption date as our date of initial application, and thus, comparative-period financial information is not presented for periods prior to the adoption date. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed us to carry forward the historical lease classification.

Adoption of the new standard resulted in total lease liabilities of $510 million and right-of-use (ROU) assets of $439 million as of January 1, 2019. The difference between the initial lease liabilities and the ROU assets is primarily related to previously existing lease liabilities. The standard did not materially impact our Consolidated Statements of Income and had no impact on our Consolidated Statements of Cash Flows. Our accounting policies under the new standard are described below. See Note 13, Leases.

Lease recognition

At inception of a contract, we determine whether an arrangement is or contains a lease. For all leases, we determine the classification as either operating or financing. Operating leases are included in Other assets, Accrued liabilities and Other noncurrent liabilities in our Consolidated Balance Sheets.

ROU assets represent our right to use an underlying asset for the lease term, and lease liabilities represent our obligation to make lease payments under the lease. Lease recognition occurs at the commencement date, and lease liability amounts are based on the present value of lease payments made during the lease term. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Because most of our leases do not provide information to determine an implicit interest rate, we use our incremental borrowing rate in determining the present value of lease payments. ROU assets also include any lease payments made prior to the commencement date less lease incentives received. Operating lease expense is recognized on a straight-line basis over the lease term.

We have lease agreements with both lease and nonlease components, which are generally accounted for together as a single lease component. In addition, for certain vehicle and equipment leases, we apply a portfolio approach to determine the lease term and discount rate.

Stock-based compensation

We have stock-based compensation plans under which various types of equity-based awards are granted, including restricted stock units (RSUs), performance units and stock options. The fair values of RSUs and stock option awards, which are subject only to service conditions with graded vesting, are recognized as compensation expense, generally on a straight-line basis over the service period, net of estimated forfeitures. The fair values of performance unit awards are recognized as compensation expense, generally on a straight-line basis from the grant date to the end of the performance period. See Note 4, Stock-based compensation.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate. Significant judgment is required in determining our provision for income taxes and income tax assets and liabilities, including evaluating uncertainties in the application of accounting principles and complex tax laws. Deferred income taxes are recorded for the expected tax consequences of temporary differences between the bases of assets and liabilities, as well as for loss and tax credit carryforwards for financial reporting purposes and amounts recognized for income tax purposes. We record a valuation allowance to reduce our deferred tax assets to the amount of future tax benefit that is more likely than not to be realized.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by tax authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits (UTBs) is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by tax authorities, new information obtained during a tax examination or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense. See Note 6, Income taxes.

Acquisitions

We first determine whether a set of assets acquired constitute a business and should be accounted for as a business combination. If the assets acquired are not a business, we account for the transaction as an asset acquisition. Business combinations are accounted for by using the acquisition method of accounting. Under the acquisition method, assets acquired, including in-process research and development (IPR&D) projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with a business combination (including the assumption of an acquiree's liability arising from an acquisition it consummated prior to our acquisition) are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in earnings. In contrast, asset acquisitions are accounted for using a cost accumulation and allocation model. Under this model, the cost of the acquisition is allocated to the assets acquired and liabilities assumed. Contingent consideration obligations incurred in connection with an asset acquisition are recorded when it is probable that they will occur and they can be reasonably estimated. See Note 2, Acquisitions, and Note 17, Fair value measurement.

Cash equivalents

We consider cash equivalents to be only those investments that are highly liquid, readily convertible to cash and which mature within three months from the date of purchase.

Interest-bearing securities

We consider our interest-bearing securities investment portfolio available-for-sale, and accordingly, these investments are recorded at fair value, with unrealized gains and losses recorded in Accumulated other comprehensive income (loss) (AOCI). Investments with maturities beyond one year may be classified as short-term marketable securities in the Consolidated Balance Sheets due to their highly liquid nature and because they represent the Company's investments that are available for current operations. See Note 9, Investments, and Note 17, Fair value measurement.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner that approximates the first-in, first-out method. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. See Note 10, Inventories.

Derivatives

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Consolidated Balance Sheets. The accounting for changes in the fair value of a derivative instrument depends on whether the derivative has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of hedging relationship. For derivatives formally designated as hedges, we assess both at inception and quarterly thereafter whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item. Our derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings. See Note 17, Fair value measurement, and Note 18, Derivative instruments.

Property, plant and equipment, net

Property, plant and equipment is recorded at historical cost, net of accumulated depreciation, amortization and, if applicable, impairment charges. We review our property, plant and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Depreciation is provided over the assets' useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms. See Note 11, Property, plant and equipment.

Goodwill and other intangible assets

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is provided over their estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note 12, Goodwill and other intangible assets.

The fair values of IPR&D projects acquired in a business combination that are not complete are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related R&D efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market the resulting products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods.

Capitalized IPR&D projects are tested for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. We consider various factors for potential impairment, including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays in obtaining marketing approval, the inability to bring a product to market and the introduction or advancement of competitors' products could result in partial or full impairment of the related intangible assets.

We perform an impairment test of goodwill annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. To date, an impairment of goodwill has not been recorded. See Note 12, Goodwill and other intangible assets.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. Certain of these proceedings are discussed in Note 19, Contingencies and commitments. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Foreign currency translation

The net assets of international subsidiaries whose local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating net assets of these subsidiaries at changing rates are recognized in AOCI. The subsidiaries' earnings are translated into U.S. dollars using average exchange rates.

Equity method investments

The equity method of accounting is used for equity investments that give us the ability to exert significant influence, but not control, over an investee based on such factors as our ownership percentage, voting and other shareholder rights, board of director representation and the existence of other collaborative or business relationships. The equity method of accounting requires us to allocate the difference between the fair value of securities acquired and our proportionate share of the carrying value of the underlying assets (the basis difference) to various items and amortize such differences over their useful lives. Our share of the investees' earnings or losses and amortization of basis differences, if any, are recorded one quarter in arrears in Interest and other income, net, in the Consolidated Statements of Income.

We record impairment losses on our equity method investments if we deem the impairment to be other-than-temporary. We deem an impairment to be other-than-temporary based on various factors, including but not limited to, the length of time the fair value is below the carrying value, volatility of the security price and our intent and ability to retain the investment to allow for a recovery in fair value.

Recent accounting pronouncements

In June 2016, the FASB issued a new accounting standard that amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the incurred-loss model with an expected-loss model. Accordingly, these financial assets are now presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the former other-than-temporary-impairment model. We adopted this standard as of January 1, 2020, using a modified-retrospective approach. Adoption of the standard did not have a material impact on our consolidated financial statements.

In March 2020, the FASB issued a new accounting standard to ease the financial reporting burdens of the expected market transition from the London Interbank Offered Rate (LIBOR) and other interbank offered rates to alternative reference rates, commonly referred to as reference rate reform. The new standard provides temporary optional expedients and exceptions to current GAAP guidance on contract modifications and hedge accounting. Specifically, a modification to transition to an alternative reference rate is treated as an event that does not require contract remeasurement or reassessment of a previous accounting treatment. Moreover, for all types of hedging relationships, an entity may change the reference rate without having to dedesignate the hedging relationship. The standard is generally effective for all contract modifications made and hedging relationships evaluated through December 31, 2022. In January 2021, the FASB issued a new accounting standard to expand on the scope of the original March 2020 standard to include derivative instruments on discounting transactions. We are currently evaluating the impact that both standards will have on our consolidated financial statements.

2. Acquisitions

Otezla® (apremilast)

On November 21, 2019, we acquired worldwide rights to Otezla®, the only oral, non-biologic treatment for psoriasis and psoriatic arthritis, along with certain related assets and liabilities, from Celgene Corporation (Celgene). Otezla® is primarily used for the treatment of patients with moderate-to-severe plaque psoriasis for whom phototherapy or systemic therapy is appropriate and is approved in more than 50 markets outside the United States, including the European Union and Japan. The acquisition was accounted for as an asset acquisition under GAAP because substantially all of the value of the assets acquired was concentrated in the global intellectual property rights of Otezla®. The operations of Otezla® have been included in our consolidated financial statements commencing on the acquisition date.

The following table summarizes the consideration transferred and the allocation of the estimated accumulated cost, including tax adjustments, to the assets acquired and liabilities assumed (in millions):

	Amounts
Cash purchase price	$ 13,400
Transaction costs	40
Accumulated cost (consideration transferred)	$ 13,440
Intangible assets:	
Developed-product-technology rights	$ 13,007
Marketing-related rights	195
Inventory	367
Deferred tax liability, net	(24)
Deferred credit	(96)
Other liabilities, net	(9)
Total assets acquired, net	$ 13,440

Amgen allocated the accumulated cost of the acquisition to the assets acquired based on their relative fair values. The accumulated cost of the acquisition includes direct acquisition-related costs and applicable taxes.

Goodwill is not recognized in the accounting for an asset acquisition. Rather, the excess of the accumulated cost over the fair value of the net assets acquired is reallocated to the nonfinancial assets acquired.

The developed-product-technology rights acquired relate to Otezla®. The estimated fair value was determined by using a multi-period excess earnings income approach, which is based on the present value of the incremental after-tax cash flows attributable only to the intangible asset. The developed-product-technology rights will be amortized over a weighted-average period of 8.5 years by using the straight-line method.

The estimated fair value of marketing-related rights, which relate to assembled workforce, was determined using a replacement cost approach, which consists of developing an estimate of the current cost of a similar new asset having the nearest equivalent utility to the asset being valued. The assembled workforce will be amortized over a period of 5 years by using the straight-line method.

The estimated fair value of the acquired inventory was determined using the comparative sales method, which uses actual or expected selling prices of inventory as the base amount to which adjustments for selling effort and a profit on the buyer's effort are applied. Inventory fair value adjustments will be amortized as inventory turns over, which we estimate to approximate 2.5 years.

Upon closing, we had a difference between the book basis and tax basis of the assets acquired. The Company used the simultaneous equations method to determine the assigned value of the net assets acquired and the related deferred tax assets or liabilities. Use of this methodology resulted in an increase to the carrying value of the intangible assets of $119 million, a net deferred tax liability of $24 million and a deferred credit of $96 million. The tax effects of the acquisition are based on Amgen's estimated blended statutory tax rate of 20%.

Nuevolution AB

On July 15, 2019, we acquired all of the outstanding stock of Nuevolution AB (Nuevolution), a publicly traded, Denmark-based biotechnology company with a leading small molecule drug discovery platform, for total consideration of $183 million in cash. The transaction, which was accounted for as a business combination, expands our ability to discover novel small molecules against difficult-to-drug targets and with greater speed and efficiency. Nuevolution's operations, which are not material, have been included in our consolidated financial statements commencing on the acquisition date.

We allocated the consideration to acquire Nuevolution to finite-lived intangible assets of $150 million, primarily comprised of technology rights for a drug discovery platform with an estimated useful life of 10 years; goodwill of $26 million, which is not tax deductible; deferred tax liabilities of $22 million; and other net assets of $29 million.

The estimated fair values of intangible assets were determined primarily by using a probability-weighted-income approach, which discounts expected future cash flows to present value by using a discount rate that represents the estimated rate that market participants would use to value the intangible assets.

Kirin-Amgen, Inc.

During the first quarter of 2018, we acquired the remaining 50% ownership of Kirin-Amgen, Inc. (K-A), from Kirin Holdings Company, Limited (Kirin), making K-A a wholly owned subsidiary of Amgen. Upon the acquisition, K-A's operations have been included in our consolidated financial statements commencing on the share acquisition date. The acquisition relieved Amgen of future royalty obligations to K-A.

Prior to the share acquisition date, we owned 50% of K-A and accounted for our interest in K-A by using the equity method of accounting.

The transaction was accounted for as a step acquisition of a business in which we were required to remeasure our existing 50% ownership interest at fair value. In addition, we were required to effectively settle our preexisting relationship with K-A, which resulted in a loss. Together the gain on the remeasurement of our existing ownership interest and the loss from the settlement of the preexisting relationship resulted in a net gain of $80 million, which was recorded in Interest and other income, net, in the Consolidated Statements of Income.

The primary means of consideration for this transaction was a payment of $780 million in cash. The aggregate share acquisition date consideration to acquire the remaining 50% ownership in K-A and the fair value of Amgen's preacquisition investment consisted of the following (in millions):

	Amounts
Total cash paid to Kirin	$ 780
Fair value of contingent consideration obligation	45
Loss on settlement of preexisting relationship	(168)
Total consideration transferred to acquire K-A	657
Fair value of Amgen's investment in K-A	825
Total acquisition date fair value	$ 1,482

In connection with this acquisition, we are obligated to make single-digit royalty payments to Kirin contingent upon sales of brodalumab. The estimated fair value of this contingent consideration obligation was $45 million as of the share acquisition date.

The fair values of assets acquired and liabilities assumed consisted of cash of $977 million, licensing rights of $470 million, deferred tax liabilities of $102 million, other assets and liabilities of $131 million and goodwill of $6 million. The estimated fair value of acquired licensing rights was determined by using a probability-related-income approach, which is based on the present value of the incremental after-tax cash flows attributable only to the intangible asset. The projected cash flows were based on certain assumptions, including estimates of future revenues and expenses and the time and resources needed to maintain the assets through commercialization. The licensing rights will be amortized over a weighted-average period of four years by using the straight-line method. The excess of the share acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $6 million was recorded as goodwill, which is not deductible for tax purposes. The $131 million in other assets and liabilities primarily represents receivables for royalties earned by K-A but not yet received, partially offset by payables representing R&D expenses incurred but not yet reimbursed by K-A.

Pro forma results of operations for this acquisition have not been presented because this acquisition was not material to our consolidated results of operations.

3. Revenues

We operate in one business segment: human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Revenues by product and by geographic area, based on customers' locations, are presented below. The majority of rest-of-world (ROW) revenues relates to products sold in Europe.

Revenues were as follows (in millions):

	Year ended December 31, 2020			Year ended December 31, 2019			Year ended December 31, 2018		
	U.S.	ROW	Total	U.S.	ROW	Total	U.S.	ROW	Total
Enbrel® (etanercept)	$ 4,855	$ 141	$ 4,996	$ 5,050	$ 176	$ 5,226	$ 4,807	$ 207	$ 5,014
Prolia® (denosumab)	1,830	933	2,763	1,772	900	2,672	1,500	791	2,291
Neulasta® (pegfilgrastim)	2,001	292	2,293	2,814	407	3,221	3,866	609	4,475
Otezla®[1]	1,790	405	2,195	139	39	178	—	—	—
XGEVA® (denosumab)	1,405	494	1,899	1,457	478	1,935	1,338	448	1,786
Aranesp® (darbepoetin alfa)	629	939	1,568	758	971	1,729	942	935	1,877
KYPROLIS® (carfilzomib)	710	355	1,065	654	390	1,044	583	385	968
Repatha® (evolocumab)	459	428	887	376	285	661	358	192	550
Other products	4,306	2,268	6,574	3,511	2,027	5,538	4,035	1,537	5,572
Total product sales[2]	17,985	6,255	24,240	16,531	5,673	22,204	17,429	5,104	22,533
Other revenues	511	673	1,184	693	465	1,158	929	285	1,214
Total revenues	$18,496	$6,928	$25,424	$17,224	$6,138	$23,362	$18,358	$5,389	$23,747

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(1) Otezla® was acquired on November 21, 2019.

(2) Hedging gains and losses, which are included in product sales, were not material for the years ended December 31, 2020, 2019 and 2018.

In the United States, we sell primarily to pharmaceutical wholesale distributors that we utilize as the principal means of distributing our products to healthcare providers. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

We had product sales to three customers, each of them accounting for more than 10% of total revenues for each of the years ended December 31, 2020, 2019 and 2018. For the year ended December 31, 2020, on a combined basis, these customers accounted for 83% of total gross revenues as shown in the following table. Certain information with respect to these customers was as follows (dollar amounts in millions):

	Years ended December 31,		
	2020	2019	2018
AmerisourceBergen Corporation:			
Gross product sales	$ 14,743	$ 12,301	$ 12,091
% of total gross revenues	34 %	33 %	33 %
McKesson Corporation:			
Gross product sales	$ 13,779	$ 11,795	$ 11,434
% of total gross revenues	32 %	31 %	31 %
Cardinal Health, Inc.:			
Gross product sales	$ 7,332	$ 6,538	$ 7,475
% of total gross revenues	17 %	17 %	20 %

As of December 31, 2020 and 2019, amounts due from these three customers each exceeded 10% of gross trade receivables and accounted for 74% and 73%, respectively, of net trade receivables on a combined basis. As of December 31, 2020 and 2019, 28% and 27%, respectively, of net trade receivables were due from customers located outside the United States, the majority of which were from Europe. Our total allowance for doubtful accounts as of December 31, 2020 and 2019, was not material.

4. Stock-based compensation

Our Amended and Restated 2009 Equity Incentive Plan (the Amended 2009 Plan) authorizes for issuance to employees of Amgen and nonemployee members of our Board of Directors shares of our common stock pursuant to grants of equity-based awards, including RSUs, stock options and performance units. The pool of shares available under the Amended 2009 Plan is reduced by one share for each stock option granted and by 1.9 shares for other types of awards granted, including RSUs and performance units (full-value awards). In general, if any shares subject to an award granted under the Amended 2009 Plan expire or become forfeited, terminated or canceled without the issuance of shares, the shares subject to such awards are added back into the authorized pool on the same basis that they were removed. In addition, under the Amended 2009 Plan, shares withheld to pay for minimum statutory tax obligations with respect to full-value awards are added back into the authorized pool on the basis of 1.9 shares. As of December 31, 2020, the Amended 2009 Plan provides for future grants and/or issuances of up to approximately 23 million shares of our common stock. Stock-based awards under our employee compensation plans are made with newly issued shares reserved for this purpose.

The following table reflects the components of stock-based compensation expense recognized in our Consolidated Statements of Income (in millions):

	Years ended December 31,		
	2020	2019	2018
RSUs	$ 178	$ 168	$ 165
Performance units	118	105	117
Stock options	34	35	29
Total stock-based compensation expense, pretax	330	308	311
Tax benefit from stock-based compensation expense	(72)	(67)	(67)
Total stock-based compensation expense, net of tax	$ 258	$ 241	$ 244

Restricted stock units and stock options

Eligible employees generally receive an annual grant of RSUs and, for certain executive-level employees, stock options, with the size and type of award generally determined by the employee's salary grade and performance level. Certain management and professional-level employees typically receive RSU grants upon commencement of employment. Nonemployee members of our Board of Directors also receive an annual grant of RSUs.

Our RSU and stock option grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including upon death, disability, termination in connection with a change in control and the retirement of employees who meet certain service and/or age requirements. RSUs and stock options generally vest in equal amounts on the second, third and fourth anniversaries of the grant date. RSUs accrue dividend equivalents, which are typically payable in shares only when and to the extent the underlying RSUs vest and are issued to the recipient.

Restricted stock units

The grant date fair value of an RSU equals the closing price of our common stock on the grant date, as RSUs accrue dividend equivalents during their vesting period. The weighted-average grant date fair values per unit of RSUs granted during the years ended December 31, 2020, 2019 and 2018, were $235.63, $182.12 and $179.18, respectively.

The following table summarizes information regarding our RSUs:

	Year ended December 31, 2020	
	Units (in millions)	Weighted-average grant date fair value
Balance nonvested as of December 31, 2019	3.1	$ 174.97
Granted	1.1	$ 235.63
Vested	(1.0)	$ 167.23
Forfeited	(0.2)	$ 190.15
Balance nonvested as of December 31, 2020	3.0	$ 198.11

The total grant date fair values of RSUs that vested during the years ended December 31, 2020, 2019 and 2018, were $161 million, $160 million and $167 million, respectively.

Stock options

The exercise price of stock options is set as the closing price of our common stock on the grant date, and the related number of shares granted is fixed at that point in time. Awards expire 10 years from the date of grant. We use the Black–Scholes option valuation model to estimate the grant date fair value of stock options.

The weighted-average assumptions used in the option valuation model and the resulting weighted-average grant date fair values of stock options granted were as follows:

	Years ended December 31,		
	2020	2019	2018
Closing price of our common stock on grant date	$ 236.36	$ 177.31	$ 177.46
Expected volatility (average of implied and historical volatility)	28.1 %	23.5 %	24.6 %
Expected life (in years)	5.8	5.8	5.8
Risk-free interest rate	0.4 %	2.4 %	2.8 %
Expected dividend yield	3.0 %	3.1 %	2.9 %
Fair value of stock options granted	$ 42.34	$ 30.47	$ 34.60

The following table summarizes information regarding our stock options:

	Year ended December 31, 2020			
	Options (in millions)	Weighted-average exercise price	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in millions)
Balance unexercised as of December 31, 2019	4.8	$ 157.00		
Granted	1.0	$ 236.36		
Exercised	(0.9)	$ 117.90		
Expired/forfeited	(0.2)	$ 178.36		
Balance unexercised as of December 31, 2020	4.7	$ 179.90	7.3	$ 243
Vested or expected to vest as of December 31, 2020	4.5	$ 178.37	7.3	$ 239
Exercisable as of December 31, 2020	1.5	$ 150.80	5.5	$ 120

The total intrinsic values of options exercised during the years ended December 31, 2020, 2019 and 2018, were $98 million, $68 million and $53 million, respectively. The actual tax benefits realized from tax deductions from option exercises during the years ended December 31, 2020, 2019 and 2018, were $21 million, $15 million and $12 million, respectively.

As of December 31, 2020, $345 million of unrecognized compensation cost was related to nonvested RSUs and unvested stock options, which is expected to be recognized over a weighted-average period of 1.8 years.

Performance units

Certain management-level employees also receive annual grants of performance units, which give the recipient the right to receive common stock that is contingent upon achievement of specified preestablished goals over the performance period, which is generally three years. The performance goals for the units granted during the years ended December 31, 2020, 2019 and 2018, which are accounted for as equity awards, are based on (i) Amgen's stockholder return compared with a comparator group of companies, which are considered market conditions and are therefore reflected in the grant date fair values of the units, and (ii) Amgen's stand-alone financial performance measures, which are considered performance conditions. The expense recognized for awards is based on the grant date fair value of a unit multiplied by the number of units expected to be earned with respect to the related performance conditions, net of estimated forfeitures. Depending on the outcome of these performance goals, a recipient may ultimately earn a number of units greater or less than the number of units granted. Shares of our common stock are issued on a one-for-one basis for each performance unit earned. In general, performance unit awards vest at the end of the performance period. The performance award program provides for accelerated or continued vesting in certain circumstances as defined in the plan, including upon death, disability, a change in control and retirement of employees who meet certain service and/or age requirements. Performance units accrue dividend equivalents that are typically payable in shares only when and to the extent the underlying performance units vest and are issued to the recipient, including with respect to market and performance conditions that affect the number of performance units earned.

We use a payout simulation model to estimate the grant date fair value of performance units. The weighted-average assumptions used in the payout simulation model and the resulting weighted-average grant date fair values of performance units granted were as follows:

	Years ended December 31,		
	2020	2019	2018
Closing price of our common stock on grant date	$ 236.36	$ 177.31	$ 177.93
Volatility	27.5 %	22.1 %	23.8 %
Risk-free interest rate	0.2 %	2.3 %	2.6 %
Fair value of units granted	$ 249.07	$ 188.40	$ 189.21

The payout simulation model assumes correlations of returns of the stock prices of our common stock and the common stocks of the comparator groups of companies and stock price volatilities of the comparator groups of companies to simulate stockholder returns over the performance periods and their resulting impact on the payout percentages based on the contractual terms of the performance units.

As of December 31, 2020 and 2019, 1.8 million and 2.0 million performance units were outstanding with weighted-average grant date fair values per unit of $207.52 and $185.64 per unit, respectively. During the year ended December 31, 2020, 0.6 million performance units with a weighted-average grant date fair value per unit of $249.07 were granted, and 0.1 million performance units with a weighted-average grant date fair value per unit of $199.86 were forfeited.

The total fair values of performance units paid during the years ended December 31, 2020, 2019 and 2018 were $230 million, $176 million and $133 million, respectively, based on the number of performance units earned multiplied by the closing stock price of our common stock on the last day of the performance period.

As of December 31, 2020, $127 million of unrecognized compensation cost was related to nonvested performance units, which is expected to be recognized over a weighted-average period of one year.

5. Defined contribution plan

The Company has defined contribution plans to which certain employees of the Company and participating subsidiaries may defer compensation for income tax purposes. Participants are eligible to receive matching contributions based on their contributions, in addition to other Company contributions. Defined contribution plan expenses were $231 million, $220 million and $173 million for the years ended December 31, 2020, 2019 and 2018, respectively.

6. Income taxes

Income before income taxes included the following (in millions):

	Years ended December 31,		
	2020	2019	2018
Domestic	$ 4,087	$ 4,371	$ 4,856
Foreign	4,046	4,767	4,689
Total income before income taxes	$ 8,133	$ 9,138	$ 9,545

The provision for income taxes included the following (in millions):

	Years ended December 31,		
	2020	2019	2018
Current provision:			
Federal	$ 921	$ 1,284	$ 1,270
State	34	39	17
Foreign	277	277	227
Total current provision	1,232	1,600	1,514
Deferred (benefit) provision:			
Federal	(321)	(276)	(317)
State	9	(22)	(7)
Foreign	(51)	(6)	(39)
Total deferred benefit	(363)	(304)	(363)
Total provision for income taxes	$ 869	$ 1,296	$ 1,151

Deferred income taxes reflect the tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards and the tax effects of net operating loss (NOL) carryforwards. Significant components of our deferred tax assets and liabilities were as follows (in millions):

	December 31,	
	2020	2019
Deferred income tax assets:		
NOL and credit carryforwards	$ 794	$ 800
Accrued expenses	561	457
Expenses capitalized for tax	144	170
Stock-based compensation	92	91
Other	301	269
Total deferred income tax assets	1,892	1,787
Valuation allowance	(571)	(517)
Net deferred income tax assets	1,321	1,270
Deferred income tax liabilities:		
Acquired intangible assets	(903)	(1,288)
Debt	(282)	(210)
Fixed assets	(148)	(53)
Other	(189)	(233)
Total deferred income tax liabilities	(1,522)	(1,784)
Total deferred income taxes, net	$ (201)	$ (514)

Valuation allowances are provided to reduce the amounts of our deferred tax assets to an amount that is more likely than not to be realized based on an assessment of positive and negative evidence, including estimates of future taxable income necessary to realize future deductible amounts.

The valuation allowance increased in 2020, primarily driven by the Company's expectation that some state R&D credits will not be utilized and that certain foreign net operating losses will expire unused.

As of December 31, 2020, we had $20 million of federal tax credit carryforwards available to reduce future federal income taxes and have provided no valuation allowance for those federal tax credit carryforwards. The federal tax credit carryforwards expire between 2023 and 2035. We had $681 million of state tax credit carryforwards available to reduce future state income taxes and have provided a valuation allowance for $585 million of those state tax credit carryforwards.

As of December 31, 2020, we had $143 million of federal NOL carryforwards available to reduce future federal income taxes and have provided a valuation allowance for $6 million of those federal NOL carryforwards. The federal NOL carryforwards, for which no valuation allowance has been provided, expire between 2021 and 2035. We had $167 million of state NOL carryforwards available to reduce future state income taxes and have provided a valuation allowance for all of the state NOL carryforwards. We had $1.9 billion of foreign NOL carryforwards available to reduce future foreign income taxes and have provided a valuation allowance for $754 million of those foreign NOL carryforwards. For the foreign NOLs with no valuation allowance provided, $861 million has no expiry; and the remainder will expire between 2021 and 2030.

The reconciliations of the total gross amounts of UTBs were as follows (in millions):

	Years ended December 31,		
	2020	2019	2018
Beginning balance	$ 3,287	$ 3,061	$ 2,953
Additions based on tax positions related to the current year	165	215	173
Additions based on tax positions related to prior years	3	22	13
Reductions for tax positions of prior years	(35)	(11)	(17)
Settlements	(68)	—	(61)
Ending balance	$ 3,352	$ 3,287	$ 3,061

Substantially all of the UTBs as of December 31, 2020, if recognized, would affect our effective tax rate. During the year ended December 31, 2020, we effectively settled certain issues with the IRS. As a result, we remeasured our UTBs accordingly.

Interest and penalties related to UTBs are included in our provision for income taxes. During the years ended December 31, 2020, 2019 and 2018, we recognized $116 million, $198 million and $137 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. The decrease in interest expense for the year ended December 31, 2020 was primarily due to lower interest rates during 2020. As of December 31, 2020 and 2019, accrued interest and penalties associated with UTBs were $783 million and $667 million, respectively.

The reconciliations between the federal statutory tax rate applied to income before income taxes and our effective tax rate were as follows:

	Years ended December 31,		
	2020	2019	2018
Federal statutory tax rate	21.0 %	21.0 %	21.0 %
Foreign earnings	(4.7)%	(4.5)%	(4.3)%
Foreign-derived intangible income	(0.7)%	(0.7)%	(0.4)%
Credits, Puerto Rico Excise Tax	(2.9)%	(2.6)%	(2.5)%
2017 Tax Act, net impact on intercompany sales	— %	— %	(1.8)%
Interest on uncertain tax positions	1.1 %	1.6 %	1.2 %
Credits, primarily federal R&D	(1.4)%	(1.0)%	(0.8)%
Audit settlements	(1.0)%	— %	(0.3)%
Other, net	(0.7)%	0.4 %	— %
Effective tax rate	10.7 %	14.2 %	12.1 %

The effective tax rates for the years ended December 31, 2020, 2019 and 2018 differ from the federal statutory rate primarily due to impacts of the jurisdictional mix of income and expenses. Substantially all of the benefit to our effective tax rate from foreign earnings results from the Company's operations in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes. Our operations in Puerto Rico are subject to tax incentive grants through 2035. Additionally, the Company's operations conducted in Singapore are subject to a tax incentive grant through 2034. Our foreign earnings are also subject to U.S. tax at a reduced rate of 10.5%.

The U.S. territory of Puerto Rico imposes an excise tax on the gross intercompany purchase price of goods and services from our manufacturing site in Puerto Rico. The rate of 4% is effective through December 31, 2027. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in cost of sales when the related products are sold. For U.S. income tax purposes, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes when the excise tax is incurred.

Income taxes paid during the years ended December 31, 2020, 2019 and 2018, were $1.4 billion, $1.9 billion and $1.9 billion, respectively.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes may arise with tax authorities involving issues regarding the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and relevant facts. In 2017, we received a Revenue Agent Report (RAR) and a modified RAR from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012 proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. However, we have been unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a Notice of Deficiency, which we would expect to vigorously contest through the judicial process. In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagree with the 2013, 2014 and 2015 proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. The IRS audit for years 2016, 2017 and 2018 is expected to start in the near term. We are also currently under examination by a number of other state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our consolidated financial statements.

We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009.

7. Earnings per share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which primarily include shares that may be issued under our stock option, restricted stock and performance unit award programs (collectively, dilutive securities), as determined by using the treasury stock method.

The computations for basic and diluted EPS were as follows (in millions, except per-share data):

	Years ended December 31,		
	2020	2019	2018
Income (Numerator):			
Net income for basic and diluted EPS	$ 7,264	$ 7,842	$ 8,394
Shares (Denominator):			
Weighted-average shares for basic EPS	586	605	661
Effect of dilutive securities	4	4	4
Weighted-average shares for diluted EPS	590	609	665
Basic EPS	$ 12.40	$ 12.96	$ 12.70
Diluted EPS	$ 12.31	$ 12.88	$ 12.62

For each of the three years ended December 31, 2020, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

8. Collaborations

A collaborative arrangement is a contractual arrangement that involves a joint operating activity. Such arrangements involve two or more parties that are both (i) active participants in the activity and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for nonrefundable upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration arrangements are performed with no guarantee of either technological or commercial success, and each arrangement is unique in nature. See Note 1, Summary of significant accounting policies, for additional discussion of revenues recognized for these types of arrangements. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line items in the Consolidated Statements of Income, net of any payments due to or reimbursements due from our collaboration partners, with such reimbursements being recognized at the time the party becomes obligated to pay. Our significant arrangements are discussed below.

BeiGene, Ltd.

On January 2, 2020, we acquired a 20.5% stake in BeiGene, Ltd. (BeiGene), for approximately $2.8 billion in cash as part of a collaboration to expand our oncology presence in China. Under the collaboration, BeiGene commenced selling XGEVA® and will commercialize KYPROLIS® and BLINCYTO® (blinatumomab) in China, and Amgen will share profits and losses equally during the initial product-specific commercialization periods; thereafter, product rights may revert to Amgen, and Amgen will pay royalties to BeiGene on sales in China of such products for a specified period.

In addition, we will jointly develop a portion of our oncology portfolio with BeiGene sharing in global R&D costs by providing cash and development services up to $1.25 billion. Upon regulatory approval, BeiGene will assume commercialization rights in China for a specified period, and Amgen and BeiGene will share profits equally until certain of these product rights revert to Amgen. Upon return of the product rights, Amgen will pay royalties to BeiGene on sales in China for a specified period. For product sales outside of China, Amgen will also pay BeiGene royalties.

During the year ended December 31, 2020, net costs recovered from BeiGene for oncology product candidates were $225 million and were recorded as an offset to R&D expense in the Consolidated Statements of Income. Profit share payments and product sales between Amgen and BeiGene were not material for the year ended December 31, 2020. As of December 31, 2020, the amount owed from BeiGene for net costs recovered was $113 million, which is included in Other current assets in the Consolidated Balance Sheets. In connection with this collaboration, we acquired an ownership interest in BeiGene. See Note 9, Investments.

Novartis Pharma AG

We are in a collaboration with Novartis Pharma AG (Novartis) to jointly develop and commercialize Aimovig® (erenumab-aooe). In the United States, Amgen and Novartis jointly develop and collaborate on the commercialization of Aimovig®. Amgen, as the principal, recognizes product sales of Aimovig® in the United States, shares U.S. commercialization costs with Novartis and pays Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig®. Novartis pays Amgen double-digit royalties on net sales of the product in the Novartis exclusive territories and funds a portion of global R&D expenses. In addition, Novartis will make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds are achieved with respect to Aimovig® in the United States. Amgen manufactures and supplies Aimovig® worldwide. The migraine collaboration will continue for the commercial life of the product unless terminated in accordance with its terms.

We are currently involved in litigation with Novartis over our collaboration agreements for the development and commercialization of Aimovig®. See Note 19, Contingencies and commitments.

During the years ended December 31, 2020 and 2019, net costs recovered from Novartis for migraine products were $192 million and $187 million, respectively, and were recorded primarily in SG&A expense in the Consolidated Statements of Income. During the year ended December 31, 2018, net costs paid to Novartis for migraine products were $44 million and were recorded primarily in SG&A expense in the Consolidated Statements of Income. During

the years ended December 31, 2020, 2019, and 2018, royalties due to Novartis for Aimovig® were $139 million, $115 million and $43 million, respectively, and were recorded in Cost of sales in the Consolidated Statements of Income. During the years ended December 31, 2020, 2019 and 2018, royalties due from Novartis for Aimovig® were not material. As a result of certain regulatory and commercial events, we received milestone payments from Novartis of $295 million during the year ended December 31, 2018, which was recorded in Other revenues in the Consolidated Statements of Income.

Bayer HealthCare LLC

We are in a licensing arrangement with Bayer HealthCare LLC (Bayer) for Nexavar®. Nexavar® is currently marketed and sold in more than 100 countries around the world for the treatment of unresectable liver cancer and advanced kidney cancer. In the United States, Nexavar® is also approved for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

In 2020, we amended the terms of our agreement with Bayer, which transferred all our operational responsibilities outside the United States to Bayer, including commercial and medical affairs activities. Prior to the amendment of the agreement, we shared equally in the profits outside the United States, excluding Japan. In lieu of this profit share, Bayer now pays us a royalty on sales of Nexavar® at a percentage rate in the low 30s. The rights to develop and market Nexavar® in Japan are reserved to Bayer. In the United States, Bayer pays us a royalty on sales of Nexavar® at a percentage rate in the high 30s.

The agreement with Bayer will terminate at the later of the date when patents expire that were issued in connection with product candidates discovered under the agreement or on the last day that we or Bayer market or sell products commercialized under the agreement anywhere in the world. Patents related to Nexavar® began to expire in 2020.

As a result of the 2020 amendment to the collaboration agreement, royalties due from Bayer for Nexavar® were $217 million and net profits were not material for the year ended December 31, 2020. During the years ended December 31, 2019 and 2018, royalties due from Bayer for Nexavar® were $79 million and $91 million, respectively. During the years ended December 31, 2019 and 2018, Amgen recorded Nexavar® net profits of $210 million and $164 million, respectively. Royalties and profit share due from Nexavar® were recorded in Other revenues in the Consolidated Statements of Income. Net R&D expenses related to the agreement were not material for the years ended December 31, 2020, 2019 and 2018.

Other

In addition to the collaborations discussed above, we have various other collaborations that are not individually significant to our business at this time. Pursuant to the terms of those agreements, we may be required to pay additional amounts or we may receive additional amounts upon the achievement of various development and commercial milestones, which in the aggregate could be significant. We may also incur or have reimbursed to us significant R&D costs if the related product candidate were to advance to late-stage clinical trials. In addition, if any products related to these collaborations are approved for sale, we may be required to pay significant royalties or we may receive significant royalties on future sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurrence.

9. Investments

Available-for-sale investments

The amortized cost, gross unrealized gains, gross unrealized losses and fair values of interest-bearing securities, all of which are considered available-for-sale, by type of security were as follows (in millions):

Types of securities as of December 31, 2020	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 129	$ 1	$ —	$ 130
U.S. Treasury bills	4,948	—	—	4,948
Corporate debt securities:				
Financial	—	—	—	—
Industrial	—	—	—	—
Other	—	—	—	—
Residential-mortgage-backed securities	—	—	—	—
Money market mutual funds	4,765	—	—	4,765
Other short-term interest-bearing securities	2	—	—	2
Total available-for-sale investments	$ 9,844	$ 1	$ —	$ 9,845

Types of securities as of December 31, 2019	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 359	$ 1	$ —	$ 360
U.S. Treasury bills	—	—	—	—
Corporate debt securities:				
Financial	1,108	13	—	1,121
Industrial	824	10	—	834
Other	195	3	—	198
Residential-mortgage-backed securities	181	1	—	182
Money market mutual funds	5,250	—	—	5,250
Other short-term interest-bearing securities	289	—	—	289
Total available-for-sale investments	$ 8,206	$ 28	$ —	$ 8,234

The fair values of available-for-sale investments by location in the Consolidated Balance Sheets were as follows (in millions):

	December 31,	
Consolidated Balance Sheets locations	2020	2019
Cash and cash equivalents	$ 5,464	$ 5,360
Marketable securities	4,381	2,874
Total available-for-sale investments	$ 9,845	$ 8,234

Cash and cash equivalents in the above table excludes bank account cash of $802 million and $677 million as of December 31, 2020 and 2019, respectively.

The fair values of available-for-sale investments by contractual maturity, except for mortgage- and asset-backed securities that do not have a single maturity date, were as follows (in millions):

	December 31,	
Contractual maturities	**2020**	**2019**
Maturing in one year or less	$ 9,795	$ 5,629
Maturing after one year through three years	50	2,304
Maturing after three years through five years	—	119
Residential-mortgage-backed securities	—	182
Total available-for-sale investments	$ 9,845	$ 8,234

For the years ended December 31, 2020, 2019 and 2018, realized gains on interest-bearing securities were $37 million, $92 million and $29 million, respectively, and realized losses on interest-bearing securities were $4 million, $36 million and $394 million, respectively. Realized gains and losses on interest-bearing securities are recorded in Interest and other income, net, in the Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

The primary objective of our investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

We review our available-for-sale investments for declines in fair value below our cost basis each quarter or whenever circumstances indicate that the cost basis of an asset may not be recoverable and assess whether the decline was due to credit-related factors or other factors. Our evaluation is based on a number of factors, including the extent to which the fair value is below our cost basis as well as adverse conditions related specifically to the security, such as any changes to the credit rating of the security and the intent to sell or whether we will more likely than not be required to sell the security before recovery of its amortized cost basis. Our assessment of whether a security is impaired could change in the future based on new developments or changes in assumptions related to that particular security.

Equity securities

We held investments in equity securities with readily determinable fair values of $477 million and $303 million as of December 31, 2020 and 2019, respectively, which are included in Other assets in the Consolidated Balance Sheets. For the years ended December 31, 2020, 2019 and 2018, net unrealized gains on publicly traded securities were $174 million, $112 million and $24 million, respectively. Realized gains and losses on publicly traded securities for the years ended December 31, 2020, 2019 and 2018, were not material.

We held investments of $203 million and $176 million in equity securities without readily determinable fair values as of December 31, 2020 and 2019, respectively, which are included in Other assets in the Consolidated Balance Sheets. Gains and losses recognized on these securities, including adjustments to the carrying values of these securities, were not material for the years ended December 31, 2020, 2019 and 2018.

Equity Method Investments

Limited partnership investments

We held limited partnership investments of $496 million and $320 million as of December 31, 2020 and 2019, respectively, which are included in Other assets in the Consolidated Balance Sheets. These investments, primarily investment funds of early-stage biotechnology companies, are accounted for by using the equity method of accounting and are measured by using our proportionate share of the net asset values of the underlying investments held by the limited partnerships as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of December 31, 2020, unfunded additional commitments to be made for these investments during the next several years were not material. For the years ended December 31, 2020, 2019 and 2018 net gains recognized from our limited partnership investments were $241 million, $27 million and $91 million, respectively.

BeiGene

On January 2, 2020, we acquired a 20.5% ownership interest in BeiGene for $2.8 billion, of which $2.6 billion was attributed to the fair value of equity securities upon closing, with the remainder attributed to prepaid R&D. Our equity investment in BeiGene is included in Other assets in the Consolidated Balance Sheets. The fair value of equity securities acquired exceeded our proportionate share of the carrying value of the underlying net assets of BeiGene by approximately $2.4 billion. This investment is accounted for by using the equity method of accounting, which requires us to identify and allocate amounts to the items that give rise to the basis difference and to amortize these items over their useful lives. This amortization, along with our share of the results of operations of BeiGene, is included in Interest and other income, net, in our Consolidated Statements of Income. Recognition occurs one quarter in arrears, which began in the second quarter of 2020. The basis difference was allocated to finite-lived intangible assets, indefinite-lived intangible assets, equity-method goodwill and related deferred taxes. The finite-lived intangible assets are being amortized over a period ranging from 8 to 15 years.

During the year ended December 31, 2020, we recognized an increase in the carrying value of our investment by purchasing additional shares to maintain our ownership interest for an aggregate cost of $569 million and recognized $34 million for the impact of other BeiGene ownership transactions. The carrying value of the investment during the year ended December 31, 2020, was reduced for our share of BeiGene's net losses of $229 million and amortization of the basis difference of $109 million.

As of December 31, 2020, the carrying value and fair value of our approximately 20.5% ownership interest in BeiGene totaled $2.9 billion and $4.9 billion, respectively. We believe that as of December 31, 2020, the carrying value of our equity investment in BeiGene is fully recoverable. For information on a collaboration agreement we entered into with BeiGene in connection with this investment, see Note 8, Collaborations.

10. Inventories

Inventories consisted of the following (in millions):

	December 31,	
	2020	2019
Raw materials	$ 486	$ 358
Work in process	2,437	2,227
Finished goods	970	999
Total inventories	$ 3,893	$ 3,584

11. Property, plant and equipment

Property, plant and equipment consisted of the following (dollar amounts in millions):

	Useful life (in years)	December 31, 2020	December 31, 2019
Land	—	$ 259	$ 263
Buildings and improvements	10-40	3,857	3,757
Manufacturing equipment	8-12	2,865	2,655
Laboratory equipment	8-12	1,257	1,236
Fixed equipment	12	2,406	2,338
Capitalized software	3-5	1,216	1,154
Other	5-10	1,091	975
Construction in progress	—	915	907
Property, plant and equipment, gross		13,866	13,285
Less accumulated depreciation and amortization		(8,977)	(8,357)
Property, plant and equipment, net		$ 4,889	$ 4,928

During the years ended December 31, 2020, 2019 and 2018, we recognized depreciation and amortization expense associated with our property, plant and equipment of $640 million, $635 million and $630 million, respectively.

Geographic information

Certain geographic information with respect to property, plant and equipment, net (long-lived assets), was as follows (in millions):

	December 31,	
	2020	2019
United States	$ 2,473	$ 2,433
Puerto Rico	1,331	1,402
ROW	1,085	1,093
Total property, plant and equipment, net	$ 4,889	$ 4,928

12. Goodwill and other intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows (in millions):

	December 31,	
	2020	2019
Beginning balance	$ 14,703	$ 14,699
Addition from acquisitions	—	26
Currency translation adjustments	(14)	(22)
Ending balance	$ 14,689	$ 14,703

Other intangible assets

Other intangible assets consisted of the following (in millions):

	December 31,					
	2020			2019		
	Gross carrying amounts	Accumulated amortization	Other intangible assets, net	Gross carrying amounts	Accumulated amortization	Other intangible assets, net
Finite-lived intangible assets:						
Developed-product-technology rights	$ 25,591	$ (10,564)	$ 15,027	$ 25,575	$ (8,322)	$ 17,253
Licensing rights	3,743	(2,791)	952	3,761	(2,398)	1,363
Marketing-related rights	1,367	(1,041)	326	1,382	(965)	417
R&D technology rights	1,317	(1,065)	252	1,273	(947)	326
Total finite-lived intangible assets	32,018	(15,461)	16,557	31,991	(12,632)	19,359
Indefinite-lived intangible assets:						
IPR&D	30	—	30	54	—	54
Total other intangible assets	$ 32,048	$ (15,461)	$ 16,587	$ 32,045	$ (12,632)	$ 19,413

Developed-product-technology rights consists of rights related to marketed products acquired in acquisitions. Licensing rights consists primarily of contractual rights acquired in acquisitions to receive future milestone, royalty and profit-sharing payments; capitalized payments to third parties for milestones related to regulatory approvals to

commercialize products; and up-front payments associated with royalty obligations for marketed products. Marketing-related rights consists primarily of rights related to the sale and distribution of marketed products. R&D technology rights pertains to technologies used in R&D that have alternative future uses.

IPR&D consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. All IPR&D projects have major risks and uncertainties associated with the timely and successful completion of the development and commercialization of product candidates, including our ability to confirm safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not permitted to market a human therapeutic without obtaining regulatory approvals, and such approvals require the completion of clinical trials that demonstrate that a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans as well as competitive product launches, affect the revenues a product can generate. Consequently, the eventual realized values, if any, of acquired IPR&D projects may vary from their estimated fair values. We review IPR&D projects for impairment annually, whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable and upon the establishment of technological feasibility or regulatory approval.

During the years ended December 31, 2020, 2019 and 2018, we recognized amortization associated with our finite-lived intangible assets of $2.8 billion, $1.4 billion and $1.3 billion, respectively. Amortization of intangible assets is included primarily in Cost of sales in the Consolidated Statements of Income. The total estimated amortization for our finite-lived intangible assets for the years ending December 31, 2021, 2022, 2023, 2024 and 2025, are $2.6 billion, $2.5 billion, $2.4 billion, $2.4 billion and $2.2 billion, respectively.

13. Leases

On January 1, 2019, we adopted a new accounting standard that amends the guidance for the accounting and reporting of leases. Certain required disclosures have been made on a prospective basis in accordance with the standard's guidance. See Note 1, Summary of significant accounting policies.

We lease certain facilities and equipment related primarily to administrative, R&D and sales and marketing activities. Leases with terms of 12 months or less are expensed on a straight-line basis over the term and are not recorded in the Consolidated Balance Sheets.

Most leases include one or more options to renew, with renewal terms that may extend the lease term up to seven years. The exercise of lease renewal options is at our sole discretion. In addition, some of our lease agreements include rental payments adjusted periodically for inflation. Our lease agreements neither contain residual value guarantees nor impose significant restrictions or covenants. We sublease certain real estate to third parties. Our sublease portfolio consists of operating leases from former R&D and administrative space.

The following table summarizes information related to our leases, all of which are classified as operating, included in our Consolidated Balance Sheets (in millions):

	December 31,	
Consolidated Balance Sheets locations	**2020**	**2019**
Assets:		
Other assets	$ 408	$ 469
Liabilities:		
Accrued liabilities	$ 153	$ 140
Other noncurrent liabilities	306	388
Total lease liabilities	$ 459	$ 528

The components of net lease costs were as follows (in millions):

	Years ended December 31,	
Lease costs	**2020**	**2019**
Operating[1]	$ 223	$ 204
Sublease income	(34)	(33)
Total net lease costs	$ 189	$ 171

(1) Includes short-term leases and variable lease costs, which were not material for the years ended December 31, 2020 and 2019.

Maturities of lease liabilities as of December 31, 2020, were as follows (in millions):

Maturity dates	Amounts
2021	$ 164
2022	132
2023	105
2024	36
2025	15
Thereafter	36
Total lease payments[1]	488
Less imputed interest	(29)
Present value of lease liabilities	$ 459

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[1] Includes future rental commitments for abandoned leases of $133 million. We expect to receive total future rental income of $107 million related to noncancelable subleases for abandoned facilities.

The weighted-average remaining lease terms and weighted-average discount rates were as follows:

	December 31,	
	2020	2019
Weighted-average remaining lease term (in years)	3.7	4.1
Weighted-average discount rate	3.1 %	3.3 %

Cash and noncash information related to our leases was as follows (in millions):

	Years ended December 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 177	$ 148
ROU assets obtained in exchange for lease obligations:		
Operating leases	$ 101	$ 163

As of December 31, 2020, we have entered into leases that have not yet commenced, with total undiscounted future lease payments of $339 million. These leases will commence in 2021 with lease terms from 30 months to 15 years.

Rental expense on operating leases under the prior lease guidance for the year ended December 31, 2018, was $166 million.

14. Other current assets and accrued liabilities

Other current assets consisted of the following (in millions):

	December 31,	
	2020	2019
Prepaid expenses	$ 1,156	$ 939
Corporate partner receivables	583	485
Tax receivables	216	186
Other	124	278
Total other current assets	$ 2,079	$ 1,888

Accrued liabilities consisted of the following (in millions):

	December 31,	
	2020	2019
Sales deductions	$ 4,801	$ 3,880
Employee compensation and benefits	1,098	981
Dividends payable	1,018	946
Income taxes payable	828	557
Sales returns reserve	474	564
Other	1,922	1,583
Total accrued liabilities	$ 10,141	$ 8,511

15. Financing arrangements

Our borrowings consisted of the following (in millions):

	December 31,	
	2020	2019
4.50% notes due 2020 (4.50% 2020 Notes)	—	300
2.125% notes due 2020 (2.125% 2020 Notes)	—	750
Floating Rate Notes due 2020	—	300
2.20% notes due 2020 (2.20% 2020 Notes)	—	700
3.45% notes due 2020 (3.45% 2020 Notes)	—	900
4.10% notes due 2021 (4.10% 2021 Notes)	—	1,000
1.85% notes due 2021 (1.85% 2021 Notes)	—	750
3.875% notes due 2021 (3.875% 2021 Notes)	—	1,750
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	1,527	1,402
2.70% notes due 2022 (2.70% 2022 Notes)	500	500
2.65% notes due 2022 (2.65% 2022 Notes)	1,500	1,500
3.625% notes due 2022 (3.625% 2022 Notes)	750	750
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	791	725
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
1.90% notes due 2025 (1.90% 2025 Notes)	500	—
3.125% notes due 2025 (3.125% 2025 Notes)	1,000	1,000
2.00% €750 million notes due 2026 (2.00% 2026 euro Notes)	916	841
2.60% notes due 2026 (2.60% 2026 Notes)	1,250	1,250
5.50% £475 million notes due 2026 (5.50% 2026 pound sterling Notes)	649	630
2.20% notes due 2027 (2.20% 2027 Notes)	1,750	—
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	957	928
2.45% notes due 2030 (2.45% 2030 Notes)	1,250	—
2.30% notes due 2031 (2.30% 2031 Notes)	1,250	—
6.375% notes due 2037 (6.375% 2037 Notes)	478	552
6.90% notes due 2038 (6.90% 2038 Notes)	254	291
6.40% notes due 2039 (6.40% 2039 Notes)	333	466
3.15% notes due 2040 (3.15% 2040 Notes)	2,000	—
5.75% notes due 2040 (5.75% 2040 Notes)	373	412
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	729	974
5.65% notes due 2042 (5.65% 2042 Notes)	415	487
5.375% notes due 2043 (5.375% 2043 Notes)	185	261
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415
3.375% notes due 2050 (3.375% 2050 Notes)	2,250	—
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
2.77% notes due 2053 (2.77% 2053 Notes)	940	—
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(1,188)	(868)
Fair value adjustments	566	296
Other	5	—
Total carrying value of debt	32,986	29,903
Less current portion	(91)	(2,953)
Total long-term debt	$ 32,895	$ 26,950

There are no material differences between the effective interest rates and the coupon rates of any of our borrowings, except for the 4.563% 2048 Notes, the 4.663% 2051 Notes and the 2.77% 2053 Notes, which have effective interest rates of 6.3%, 5.6% and 5.2%, respectively.

Under the terms of all of our outstanding notes, except our Other notes due 2097, in the event of a change-in-control triggering event we may be required to purchase all or a portion of these debt securities at prices equal to 101% of the principal amounts of the notes plus accrued and unpaid interest. In addition, all of our outstanding notes —except our 0.41% 2023 Swiss franc Bonds and Other notes due 2097—may be redeemed at any time at our option —in whole or in part—at the principal amounts of the notes being redeemed plus accrued and unpaid interest and make-whole amounts, which are defined by the terms of the notes. Certain of the redeemable notes do not require the payment of make-whole amounts if redeemed during a specified period of time immediately prior to the maturity of the notes. Such time periods range from one month to six months prior to maturity.

Debt issuances

During the year ended December 31, 2020, we issued debt securities in the following offerings:

- In February 2020, we issued $5.0 billion of debt consisting of $500 million of the 1.90% 2025 Notes, $750 million of the 2.20% 2027 Notes, $1.25 billion of the 2.45% 2030 Notes, $1.25 billion of the 3.15% 2040 Notes and $1.25 billion of the 3.375% 2050 Notes.
- In May 2020, we issued $4.0 billion of debt consisting of $1.0 billion of the 2.20% 2027 Notes, $750 million of the 3.15% 2040 Notes and $1.0 billion of the 3.375% 2050 Notes, which represents a further issuance of, and which forms a single series with, each of the corresponding series of notes issued in February 2020, and $1.25 billion of the 2.30% 2031 Notes.

We did not issue any debt or debt securities during the years ended December 31, 2019 and 2018.

Debt repayments/redemptions

We made debt repayments/redemptions during the years ended December 31, 2020, 2019 and 2018 as follows:

- In 2020, we repaid/redeemed $6.5 billion of debt, including the repayment at maturity of the $300 million aggregate principal amount of the 4.50% 2020 Notes, the $750 million aggregate principal amount of the 2.125% 2020 Notes, the $300 million Floating Rate Notes due 2020 and the $700 million aggregate principal amount of the 2.20% 2020 Notes. In connection with the redemption of the $900 million aggregate principal amount of the 3.45% 2020 Notes, the $1.0 billion aggregate principal balance of the 4.10% 2021 Notes, the $750 million aggregate principal balance of the 1.85% 2021 Notes and the $1.75 billion aggregate principal balance of the 3.875% 2021 Notes, we paid a total of $96 million in make-whole amounts plus associated accrued and unpaid interest, all of which was recognized in Interest expense, net, in the Consolidated Statements of Income.
- In 2019, we repaid $4.5 billion of debt, including the $1.4 billion aggregate principal amount of the 2.20% 2019 Notes, the $1.0 billion aggregate principal amount of the 5.70% 2019 Notes, the €675 million aggregate principal amount ($864 million upon settlement of the related cross-currency swap) of the 2.125% 2019 euro Notes, the $700 million aggregate principal amount of the 1.90% 2019 Notes and the $550 million Floating Rate Notes due 2019.
- In 2018, we repaid $1.1 billion of debt, including the $500 million aggregate principal amount of the 6.15% 2018 Notes and the €550 million aggregate principal amount of the 4.375% 2018 Notes revalued at $621 million upon maturity.

Interest rate swaps

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted fixed-rate interest coupons for certain of our debt issuances to floating LIBOR-based coupons over the lives of the respective notes. These interest rate swap contracts qualified and are designated as fair value hedges.

In connection with the redemption of certain of the notes discussed above, associated interest rate swap contracts with an aggregate notional value of $3.65 billion were terminated. In addition, because of historically low interest rates, during the year ended December 31, 2020, we terminated interest rate swaps with an aggregate notional amount of $5.2 billion that hedged the 3.625% 2024 Notes, the 2.60% 2026 Notes, the 4.663% 2051 Notes and portions of the 3.625% 2022 Notes and the 3.125% 2025 Notes, which resulted in the receipt of $576 million of cash and reduced counterparty credit risk. Immediately following the terminations of these contracts, we entered into

new interest rate swap agreements at then-current interest rates on the same $5.2 billion principal amount of notes. See Note 18, Derivative instruments.

The effective interest rates on notes for which we have entered into interest rate swap contracts and the related notional amounts of these contracts were as follows (dollar amounts in millions):

	December 31, 2020		December 31, 2019	
Notes	Notional amounts	Effective interest rates	Notional amounts	Effective interest rates
3.45% 2020 Notes	$ —	LIBOR + 1.1%	$ 900	LIBOR + 1.1%
4.10% 2021 Notes	—	LIBOR + 1.7%	1,000	LIBOR + 1.7%
3.875% 2021 Notes	—	LIBOR + 2.0%	1,750	LIBOR + 2.0%
3.625% 2022 Notes	750	LIBOR + 2.7%	750	LIBOR + 1.6%
3.625% 2024 Notes	1,400	LIBOR + 3.2%	1,400	LIBOR + 1.4%
3.125% 2025 Notes	1,000	LIBOR + 1.8%	1,000	LIBOR + 0.9%
2.60% 2026 Notes	1,250	LIBOR + 1.8%	1,250	LIBOR + 0.3%
4.663% 2051 Notes[1]	1,500	LIBOR + 2.6%	1,500	LIBOR + 0.0%
Total notional amounts	$ 5,900		$ 9,550	

[1] Excludes an additional 1.5% of interest for the difference between the coupon rate paid to noteholders and the fixed rate received under the interest rate swap contracts.

Debt exchange

In 2020, we completed a private offering to exchange portions of certain outstanding senior notes due 2037 through 2043 (collectively, Old Notes), listed below, for the $940 million principal amount of the newly issued 2.77% 2053 Notes (the Exchange Offer).

The following principal amounts of each series of Old Notes were validly tendered and subsequently cancelled in connection with the Exchange Offer (in millions):

	Principal amount exchanged
6.375% 2037 Notes	$ 74
6.90% 2038 Notes	37
6.40% 2039 Notes	133
5.75% 2040 Notes	39
5.15% 2041 Notes	245
5.65% 2042 Notes	72
5.375% 2043 Notes	76

The 2.77% 2053 Notes bear interest at a lower fixed coupon rate while requiring higher principal repayment at a later maturity date as compared to those of the Old Notes that were exchanged. There were no other significant changes to the terms between the Old Notes and the 2.77% 2053 Notes. In connection with the Exchange Offer, $85 million was paid to holders of the Old Notes (the cash consideration).

The Exchange Offer was accounted for as a debt modification, and accordingly, deferred financing costs and discounts associated with the Old Notes, the cash consideration and the $264 million discount associated with the 2.77% 2053 Notes are being accreted over the term of these newly issued notes and recorded as Interest expense, net, in the Consolidated Statements of Income.

Cross-currency swaps

In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. The terms of these contracts effectively convert the interest payments and principal repayments on our 1.25% 2022 euro Notes, 0.41% 2023 Swiss franc Bonds, 2.00% 2026 euro Notes, 5.50% 2026 pound sterling Notes and 4.00% 2029 pound sterling Notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts have been designated as cash flow hedges. For information regarding the terms of these contracts, see Note 18, Derivative instruments.

Shelf registration statement and other facilities

As of December 31, 2020, we have a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. As of December 31, 2020 and 2019, we had no amounts outstanding under our commercial paper program.

In 2019, we amended and restated our $2.5 billion syndicated, unsecured, revolving credit agreement, which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $750 million with the agreement of the banks. Each bank that is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest for any amounts borrowed under this facility, based on our current credit rating, at (i) LIBOR plus 1% or (ii) the highest of (A) the syndication agent bank base commercial lending rate, (B) the overnight federal funds rate plus 0.50% or (C) one-month LIBOR plus 1%. The agreement contains provisions relating to the determination of successor rates to address the possible phase-out or unavailability of designated reference rates. As of December 31, 2020 and 2019, no amounts were outstanding under this facility.

In February 2020, we filed a shelf registration statement with the U.S. Securities and Exchange Commission that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depository shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depository shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2023.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which requires us to maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2020.

Contractual maturities of debt obligations

The aggregate contractual maturities of all borrowings due subsequent to December 31, 2020, are as follows (in millions):

Maturity dates	Amounts
2021	$ —
2022	4,277
2023	1,541
2024	1,400
2025	1,500
Thereafter	24,890
Total	$ 33,608

Interest costs

Interest costs are expensed as incurred except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest costs capitalized for the years ended December 31, 2020, 2019 and 2018, were not material. Interest paid, including the ongoing impact of interest rate and cross-currency swap contracts, during the years ended December 31, 2020, 2019 and 2018, were $1.2 billion, $1.3 billion and $1.5 billion, respectively.

16. Stockholders' equity

Stock repurchase program

Activity under our stock repurchase program, on a trade date basis, was as follows (in millions):

	Years ended December 31,					
	2020		2019		2018	
	Shares	Dollars	Shares*	Dollars	Shares*	Dollars
First quarter	4.3	$ 933	15.9	$ 3,031	56.4	$ 10,787
Second quarter	2.6	591	13.1	2,349	18.2	3,190
Third quarter	3.0	752	6.2	1,170	8.7	1,713
Fourth quarter	5.3	1,221	5.1	1,090	11.1	2,165
Total stock repurchases	15.2	$ 3,497	40.2	$ 7,640	94.5	$ 17,855

* Total shares do not add due to rounding.

In December 2019, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $4.0 billion. As of December 31, 2020, $3.0 billion remained available under our stock repurchase program.

Dividends

Our Board of Directors declared quarterly dividends per share of $1.60, $1.45 and $1.32, which were paid in each of the four quarters of 2020, 2019 and 2018, respectively.

Historically, we have declared dividends in December of each year, which were paid in the first quarter of the following fiscal year and in March, July and October, which were paid in the second, third and fourth quarters, respectively, of the same fiscal year. Additionally, on December 16, 2020, the Board of Directors declared a quarterly cash dividend of $1.76 per share of common stock, which will be paid on March 8, 2021, to all stockholders of record as of the close of business on February 15, 2021.

Accumulated other comprehensive loss

The components of AOCI were as follows (in millions):

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2017	$ (529)	$ (6)	$ (144)	$ —	$ (679)
Cumulative effect of change in accounting principle, net of tax	—	—	(9)	—	(9)
Foreign currency translation adjustments	(141)	—	—	—	(141)
Unrealized gains (losses)	—	61	(556)	—	(495)
Reclassification adjustments to income	—	262	365	—	627
Other losses	—	—	—	(2)	(2)
Income taxes	—	(76)	6	—	(70)
Balance as of December 31, 2018	(670)	241	(338)	(2)	(769)
Foreign currency translation adjustments	(48)	—	—	—	(48)
Unrealized gains	—	127	424	—	551
Reclassification adjustments to income	—	(211)	(56)	—	(267)
Other losses	—	—	—	(5)	(5)
Income taxes	—	18	(8)	—	10
Balance as of December 31, 2019	(718)	175	22	(7)	(528)
Foreign currency translation adjustments	9	—	—	—	9
Unrealized (losses) gains	—	(61)	6	—	(55)
Reclassification adjustments to income	—	(501)	(33)	—	(534)
Other losses	—	—	—	(7)	(7)
Income taxes	—	124	6	—	130
Balance as of December 31, 2020	$ (709)	$ (263)	$ 1	$ (14)	$ (985)

With respect to the table above, income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for cash flow hedges were a $14 million benefit and a $110 million benefit in 2020, a $28 million expense and a $46 million benefit in 2019 and a $21 million expense and a $55 million expense in 2018, respectively. Income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for available-for-sale securities were a $1 million expense and a $7 million benefit in 2020, a $22 million expense and a $14 million benefit in 2019 and a $9 million benefit and a $3 million expense in 2018, respectively.

Reclassifications out of AOCI and into earnings were as follows (in millions):

Components of AOCI	Years ended December 31, 2020	2019	2018	Consolidated Statements of Income locations
Cash flow hedges:				
Foreign currency contract gains (losses)	$ 178	$ 101	$ (21)	Product sales
Cross-currency swap contract gains (losses)	323	110	(241)	Interest and other income, net
	501	211	(262)	Income before income taxes
	(110)	(46)	55	Provision for income taxes
	$ 391	$ 165	$ (207)	Net income
Available-for-sale securities:				
Net realized gains (losses)	$ 33	$ 56	$ (365)	Interest and other income, net
	(7)	(14)	3	Provision for income taxes
	$ 26	$ 42	$ (362)	Net income

Other

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. As of December 31, 2020 and 2019, no shares of preferred stock were issued or outstanding.

17. Fair value measurement

To estimate the fair value of our financial assets and liabilities, we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing an asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing an asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

Level 1	— Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access
Level 2	— Valuations for which all significant inputs are observable either directly or indirectly—other than Level 1 inputs
Level 3	— Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

The fair values of each major class of the Company's financial assets and liabilities measured at fair value on a recurring basis were as follows (in millions):

Fair value measurement as of December 31, 2020, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	$ 130	$ —	$ —	$ 130
U.S. Treasury bills	4,948	—	—	4,948
Corporate debt securities:				
Financial	—	—	—	—
Industrial	—	—	—	—
Other	—	—	—	—
Residential-mortgage-backed securities	—	—	—	—
Money market mutual funds	4,765	—	—	4,765
Other short-term interest-bearing securities	—	2	—	2
Equity securities	477	—	—	477
Derivatives:				
Foreign currency contracts	—	28	—	28
Cross-currency swap contracts	—	255	—	255
Interest rate swap contracts	—	66	—	66
Total assets	$ 10,320	$ 351	$ —	$ 10,671
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 237	$ —	$ 237
Cross-currency swap contracts	—	318	—	318
Interest rate swap contracts	—	15	—	15
Contingent consideration obligations	—	—	33	33
Total liabilities	$ —	$ 570	$ 33	$ 603

Fair value measurement as of December 31, 2019, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	$ 360	$ —	$ —	$ 360
U.S. Treasury bills	—	—	—	—
Corporate debt securities:				
Financial	—	1,121	—	1,121
Industrial	—	834	—	834
Other	—	198	—	198
Residential-mortgage-backed securities	—	182	—	182
Money market mutual funds	5,250	—	—	5,250
Other short-term interest-bearing securities	—	289	—	289
Equity securities	303	—	—	303
Derivatives:				
Foreign currency contracts	—	224	—	224
Cross-currency swap contracts	—	66	—	66
Interest rate swap contracts	—	259	—	259
Total assets	$ 5,913	$ 3,173	$ —	$ 9,086
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 31	$ —	$ 31
Cross-currency swap contracts	—	315	—	315
Interest rate swap contracts	—	—	—	—
Contingent consideration obligations	—	—	61	61
Total liabilities	$ —	$ 346	$ 61	$ 407

Interest-bearing and equity securities

The fair values of our U.S. Treasury securities, money market mutual funds and equity securities are based on quoted market prices in active markets, with no valuation adjustment.

We estimate the fair values of our corporate debt securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry-standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

We estimate the fair values of our residential-mortgage-backed securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry-standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment or default projections based on historical data; and other observable inputs.

We value our other short-term interest-bearing securities at amortized cost, which approximates fair value given their near-term maturity dates.

Derivatives

All of our foreign currency forward and option derivative contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A– or equivalent by Standard & Poor's Financial Services (S&P), Moody's Investors Service, Inc. (Moody's) or Fitch Ratings, Inc. (Fitch). We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. These inputs, when applicable, are at commonly quoted intervals. See Note 18, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. See Note 18, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by using an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include LIBOR, swap rates and obligor credit default swap rates. See Note 18, Derivative instruments.

During the years ended December 31, 2020 and 2019, there were no transfers of assets or liabilities between fair value measurement levels, and there were no material remeasurements to the fair values of assets and liabilities that are not measured at fair value on a recurring basis. During the year ended December 31, 2018, we discontinued the internal development of a program that resulted in an impairment of an IPR&D asset of $330 million, which was recognized in Other operating expenses in the Consolidated Statements of Income and included in Other items, net, in the Consolidated Statements of Cash Flows.

Summary of the fair values of other financial instruments

Cash equivalents

The fair values of cash equivalents approximate their carrying values due to the short-term nature of such financial instruments.

Borrowings

We estimated the fair values of our borrowings by using Level 2 inputs. As of December 31, 2020 and 2019, the aggregate fair values of our borrowings were $39.4 billion and $33.7 billion, respectively, and the carrying values were $33.0 billion and $29.9 billion, respectively.

Investment in BeiGene

We estimated the fair value of our investment in BeiGene by using Level 1 inputs. As of December 31, 2020, the fair value and carrying value were $4.9 billion and $2.9 billion, respectively.

18. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we use or have used certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We do not use derivatives for speculative trading purposes.

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates associated primarily with our euro-denominated international product sales. Increases and decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are partially offset by corresponding increases and decreases in the

cash flows from our international operating expenses resulting from these foreign currency exchange rate movements. To further reduce our exposure to foreign currency exchange rate fluctuations with regard to our international product sales, we enter into foreign currency forward and option contracts to hedge a portion of our projected international product sales primarily over a three-year time horizon, with, at any given point in time, a higher percentage of nearer-term projected product sales being hedged than in successive periods.

As of December 31, 2020, 2019 and 2018, we had outstanding foreign currency forward contracts with aggregate notional amounts of $5.1 billion, $5.0 billion and $4.5 billion, respectively. As of December 31, 2018 we had outstanding foreign currency option contracts with aggregate notional amounts of $21 million, and no such outstanding contracts as of December 31, 2020 and 2019. We have designated these foreign currency forward and foreign currency option contracts, which are primarily euro based, as cash flow hedges. Accordingly, we report the unrealized gains and losses on these contracts in AOCI in the Consolidated Balance Sheets, and we reclassify them to Product sales in the Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term debt denominated in foreign currencies, we enter into cross-currency swap contracts. Under the terms of such contracts, we paid euros, pounds sterling and Swiss francs and received U.S. dollars for the notional amounts at the inception of the contracts; and based on these notional amounts, we exchange interest payments at fixed rates over the lives of the contracts by paying U.S. dollars and receiving euros, pounds sterling and Swiss francs. In addition, we will pay U.S. dollars to and receive euros, pounds sterling and Swiss francs from the counterparties at the maturities of the contracts for these same notional amounts. The terms of these contracts correspond to the related hedged debt, thereby effectively converting the interest payments and principal repayment on the debt from euros, pounds sterling and Swiss francs to U.S. dollars. We have designated these cross-currency swap contracts as cash flow hedges. Accordingly, the unrealized gains and losses on these contracts are reported in AOCI in the Consolidated Balance Sheets and reclassified to Interest and other income, net, in the Consolidated Statements of Income in the same periods during which the hedged debt affects earnings.

The notional amounts and interest rates of our cross-currency swaps as of December 31, 2020, were as follows (notional amounts in millions):

	Foreign currency			U.S. dollars	
Hedged notes	**Notional amounts**		**Interest rates**	**Notional amounts**	**Interest rates**
1.25% 2022 euro Notes	€	1,250	1.3 %	$ 1,388	3.2 %
0.41% 2023 Swiss franc Bonds	CHF	700	0.4 %	$ 704	3.4 %
2.00% 2026 euro Notes	€	750	2.0 %	$ 833	3.9 %
5.50% 2026 pound sterling Notes	£	475	5.5 %	$ 747	6.0 %
4.00% 2029 pound sterling Notes	£	700	4.0 %	$ 1,111	4.5 %

During the year ended December 31, 2019, our 2.125% 2019 euro Notes matured, and the related cross-currency swaps were settled.

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Consolidated Balance Sheets and are amortized into Interest expense, net, in the Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the year ended December 31, 2020, and amounts expected to be recognized during the subsequent 12 months are not material.

The unrealized losses and gains recognized in AOCI for our derivative instruments designated as cash flow hedges were as follows (in millions):

	Years ended December 31,		
Derivatives in cash flow hedging relationships	**2020**	**2019**	**2018**
Foreign currency contracts	$ (251)	$ 148	$ 348
Cross-currency swap contracts	190	(21)	(287)
Forward interest rate contracts	—	—	—
Total unrealized (losses) gains	$ (61)	$ 127	$ 61

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified for and were designated as fair value hedges. These interest rate swap contracts effectively convert fixed-rate coupons to floating-rate LIBOR-based coupons over the terms of the related hedge contracts. As of December 31, 2020 and 2019, we had interest rate swap contracts with aggregate notional amounts of $5.9 billion and $9.6 billion, respectively, that hedge certain portions of our long-term debt issuances.

Interest rate swaps with an aggregate notional value of $3.7 billion were terminated during the year ended December 31, 2020, in connection with the redemption of certain of our notes. The terminations of these interest rate swaps resulted in a gain of $40 million, recognized in Interest expense, net, in the Consolidated Statements of Income. Additionally, we terminated $5.2 billion aggregate notional amount of interest rate swaps, which resulted in the receipt of $576 million from the counterparties that was included in Net cash provided by operating activities in the Consolidated Statements of Cash Flows for the year ended December 31, 2020. This amount will be recognized as a reduction in Interest expense, net, in the Consolidated Statements of Income over the remaining life of the underlying notes. Immediately following the terminations of these interest rate swap contracts, we entered into new interest rate swap agreements at then-current interest rates on the same $5.2 billion principal amount of notes. See Note 15, Financing arrangements, for information on our interest rate swaps.

For interest rate swap contracts that qualify for and are designated as fair value hedges, we recognize in Interest expense, net, in the Consolidated Statements of Income the unrealized gain or loss on the derivative resulting from the change in fair value during the period, as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. If a hedging relationship involving an interest rate swap contract is terminated, the gain or loss realized on contract termination is recorded as an adjustment to the carrying value of the debt and amortized into Interest expense, net, over the remaining life of the previously hedged debt.

The hedged liabilities and related cumulative-basis adjustments for fair value hedges of those liabilities were recorded in the Consolidated Balance Sheets as follows (in millions):

	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
	December 31,		December 31,	
Consolidated Balance Sheets locations	2020	2019	2020	2019
Current portion of long-term debt	$ 89	$ 903	$ 89	$ 4
Long-term debt	$ 6,258	$ 8,814	$ 477	$ 292

(1) Current portion of long-term debt includes $89 million of carrying value with discontinued hedging relationships as of December 31, 2020. Long-term debt includes $525 million and $136 million of carrying value with discontinued hedging relationships as of December 31, 2020, and December 31, 2019, respectively.

(2) Current portion of long-term debt includes $89 million of hedging adjustments on discontinued hedging relationships as of December 31, 2020. Long-term debt includes $425 million and $36 million of hedging adjustments on discontinued hedging relationships as of December 31, 2020, and December 31, 2019, respectively.

Impact of hedging transactions

The following tables summarize the amounts recorded in income and expense line items and the effects thereon from fair value and cash flow hedging, including discontinued hedging relationships (in millions):

	Year ended December 31, 2020		
	Product sales	Interest and other income, net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 24,240	$ 256	$ (1,262)
The effects of cash flow and fair value hedging:			
Gains on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ 178	$ —	$ —
Cross-currency swap contracts	$ —	$ 323	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ 315
Derivatives designated as hedging instruments	$ —	$ —	$ (204)

	Year ended December 31, 2019		
	Product sales	Interest and other income, net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 22,204	$ 753	$ (1,289)
The effects of cash flow and fair value hedging:			
Gains on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ 101	$ —	$ —
Cross-currency swap contracts	$ —	$ 110	$ —
(Losses) gains on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ (349)
Derivatives designated as hedging instruments	$ —	$ —	$ 352

	Year ended December 31, 2018		
	Product sales	Interest and other income (expense), net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 22,533	$ 674	$ (1,392)
The effects of cash flow and fair value hedging:			
(Losses) on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ (21)	$ —	$ —
Cross-currency swap contracts	$ —	$ (241)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ 65
Derivatives designated as hedging instruments	$ —	$ —	$ (42)

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[1] Gains on hedged items do not completely offset losses on the related designated hedging instruments due to amortization of the cumulative amounts of fair value hedging adjustments included in the carrying amount of the

hedged debt for discontinued hedging relationships and the recognition of gains on terminated hedges where the corresponding hedged item was paid down in the period.

No portions of our cash flow hedge contracts were excluded from the assessment of hedge effectiveness. As of December 31, 2020, we expected to reclassify $136 million of net losses on our foreign currency and cross-currency swap contracts out of AOCI and into earnings during the next 12 months.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations in certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. Most of these exposures are hedged on a month-to-month basis. As of December 31, 2020, 2019 and 2018, the total notional amounts of these foreign currency forward contracts were $1.0 billion, $1.2 billion and $737 million, respectively. Gains and losses recognized in earnings for our derivative instruments not designated as hedging instruments were not material for the years ended December 31, 2020, 2019 and 2018.

The fair values of derivatives included in the Consolidated Balance Sheets were as follows (in millions):

	Derivative assets		Derivative liabilities	
December 31, 2020	**Consolidated Balance Sheets locations**	**Fair values**	**Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 28	Accrued liabilities/ Other noncurrent liabilities	$ 237
Cross-currency swap contracts	Other current assets/ Other assets	255	Accrued liabilities/ Other noncurrent liabilities	318
Interest rate swap contracts	Other current assets/ Other assets	66	Accrued liabilities/ Other noncurrent liabilities	15
Total derivatives designated as hedging instruments		349		570
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	—	Accrued liabilities	—
Total derivatives not designated as hedging instruments		—		—
Total derivatives		$ 349		$ 570

	Derivative assets		Derivative liabilities	
December 31, 2019	**Consolidated Balance Sheets locations**	**Fair values**	**Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 223	Accrued liabilities/ Other noncurrent liabilities	$ 31
Cross-currency swap contracts	Other current assets/ Other assets	66	Accrued liabilities/ Other noncurrent liabilities	315
Interest rate swap contracts	Other current assets/ Other assets	259	Accrued liabilities/ Other noncurrent liabilities	—
Total derivatives designated as hedging instruments		548		346
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	1	Accrued liabilities	—
Total derivatives not designated as hedging instruments		1		—
Total derivatives		$ 549		$ 346

Our derivative contracts that were in liability positions as of December 31, 2020, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our, or the surviving entity's, creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right but not the obligation to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the contracts may be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

The cash flow effects of our derivative contracts in the Consolidated Statements of Cash Flows are included in Net cash provided by operating activities, except for the settlement of notional amounts of cross-currency swaps, which are included in Net cash used in financing activities.

19. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See Part I, Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations.* We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote.

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Our legal proceedings involve various aspects of our business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing, in which we could incur a liability, our opponents seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process, which in complex proceedings of the sort we face often extend for several years. As a result, none of the matters described in this filing, in which we could incur a liability, have progressed sufficiently through discovery and/or the development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain recent developments concerning our legal proceedings and other matters are discussed below:

Abbreviated New Drug Application (ANDA) Patent Litigation

KYPROLIS® ANDA Patent Litigation

Onyx Therapeutics, Inc. v. Cipla Limited, et al.

Between October 2016 and April 2018, Onyx Therapeutics, Inc. (Onyx Therapeutics, a wholly-owned subsidiary of Amgen), filed separate lawsuits in the U.S. District Court for the District of Delaware (the Delaware District Court) against: (1) Cipla Limited and Cipla USA, Inc. (collectively, Cipla); (2) Sagent Pharmaceuticals, Inc. (Sagent); (3) Breckenridge Pharmaceutical, Inc. (Breckenridge); and (4) Fresenius Kabi, USA LLC, Fresenius Kabi USA, Inc., Fresenius Kabi Pharmaceuticals Holding, Inc. and Fresenius Kabi Oncology Limited; (5) Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.; (6) MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (collectively, MSN); (7) Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL); (8) Qilu Pharma, Inc. and Qilu Pharmaceutical Co. Ltd. (collectively, Qilu); (9) Apotex Inc. and Apotex Corp. (Apotex); (10) InnoPharma, Inc. (InnoPharma); and (11) Aurobindo Pharma USA, Inc., each for infringement of one or more of our following patents, which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) for KYPROLIS®: U.S. Patent Nos. 7,232,818 (the '818 Patent), 7,417,042 (the '042 Patent), 7,491,704 (the '704 Patent), 7,737,112 (the '112 Patent), 8,129,346 (the '346 Patent), 8,207,125 (the '125 Patent), 8,207,126 (the '126 Patent), 8,207,127 (the '127 Patent) and 8,207,297 (the '297 Patent). Each of these lawsuits was based on each defendant's submission of an ANDA seeking U.S. Food and Drug Administration (FDA) approval to market a generic version of KYPROLIS®. In each lawsuit, Onyx Therapeutics sought an order of the Delaware District Court making any FDA approval of the respective defendant's ANDA effective no earlier than the expiration of the applicable patents. The Delaware District Court consolidated these lawsuits for purposes of discovery into a single case, *Onyx Therapeutics, Inc. v. Cipla Limited, et al.*

In January 2017, by stipulation with Onyx Therapeutics, Fresenius Kabi Pharmaceuticals Holding, Inc. and Fresenius Kabi Oncology Limited were dismissed from the lawsuit, leaving Fresenius Kabi, USA LLC and Fresenius Kabi USA, Inc. (collectively, Fresenius) as the remaining Fresenius defendants. In September 2017 and February 2018, respectively, by joint stipulation with Onyx Therapeutics, Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. were each dismissed from the lawsuit, and in February 2018, Qilu was dismissed from the lawsuit by joint stipulation between Onyx Therapeutics and Qilu. Between April and July of 2018, the Delaware District Court entered orders on stipulations between Onyx Therapeutics and each of Apotex, DRL, Sagent, Fresenius, Breckenridge, Aurobindo Pharma USA, Inc., Cipla and InnoPharma, respectively, that each defendant infringes the '042, '112, '125, '126 and '127 Patents. Onyx Therapeutics provided those defendants, either through a stipulated order or other agreement, a covenant that it would not assert patent infringement of the '818,'704,'346 and '297 Patents against certain of the respective defendants' ANDA applications and products. In June 2018, the Delaware District Court entered an order on a stipulation between Onyx Therapeutics and MSN that MSN infringes the '112 Patent. In December 2018, Apotex, DRL, Fresenius, InnoPharma, Sagent, Breckenridge, Aurobindo Pharma USA, Inc. and Cipla amended their responses to the complaints to add the defense of unclean hands and to seek declarations of unenforceability of the asserted patents based on allegations of inequitable conduct. In January 2019, MSN amended its responses to the complaints to add the defense of unclean hands.

On January 11, 2019, Onyx Therapeutics filed a separate lawsuit in the Delaware District Court against Breckenridge for infringement of the '042, '112 and '125 Patents in connection with its ANDA that seeks approval to market generic versions of KYPROLIS®. On March 4, 2019, the Delaware District Court entered an order on a stipulation between Onyx Therapeutics and Breckenridge, providing that Breckenridge infringes the asserted claims of the '042, '112 and '125 Patents, and consolidated this lawsuit against Breckenridge into the existing consolidated case, *Onyx Therapeutics, Inc. v. Cipla Limited, et al.*, for all purposes.

On May 6, 2019, the Delaware District Court commenced trial in the *Onyx Therapeutics, Inc. v. Cipla Limited, et al.* consolidated case. During trial, the Delaware District Court signed consent judgments filed by Onyx Therapeutics and each of Aurobindo Pharma USA, Inc., InnoPharma, Sagent, Apotex, Fresenius, DRL and Breckenridge, in which the parties stipulated to entry of: (1) judgment dismissing with prejudice all of the parties' claims, counterclaims, affirmative defenses and demands; and (2) an injunction prohibiting infringement of the '042, '112 and '125 Patents by the manufacture, use, sale, offer to sell or importation into the United States of the applicable defendant's carfilzomib product unless specifically authorized pursuant to the applicable confidential settlement agreement. During trial, the Delaware District Court also entered a consent judgment between Onyx

Therapeutics and MSN, in which the parties stipulated to entry of: (1) judgment dismissing with prejudice all of the parties' claims, counterclaims, affirmative defenses and demands; and (2) an injunction prohibiting infringement of the '112 Patent by the manufacture, use, sale, offer to sell or importation into the United States of MSN's carfilzomib product unless specifically authorized pursuant to the confidential settlement agreement. On May 16, 2019, trial concluded between Onyx Therapeutics and the lone remaining defendant, Cipla.

On May 8, 2020, consistent with its May 4, 2020 decision and order, the Delaware District Court entered final judgment in favor of Onyx Therapeutics and against Cipla on infringement, validity and enforceability of claims 23 and 24 of the ’042 Patent, claim 1 of the ’125 Patent and claim 31 of the ’112 Patent. The Delaware District Court entered judgment in favor of Cipla and against Onyx Therapeutics on Cipla’s counterclaim for invalidity of claim 32 of the ’112 Patent and ordered that the effective date of any final approval by the FDA of Cipla’s ANDA must be after expiration of the three asserted patents (the ’042, ’125 and ’112 Patents) and any regulatory exclusivity to which Onyx Therapeutics may become entitled. The final judgment includes an injunction prohibiting Cipla from making, using, offering to sell, selling or importing into the United States Cipla’s carfilzomib product during the term of the three asserted patents. On May 29, 2020, Cipla filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court). The Federal Circuit Court has set the hearing date on Cipla’s appeal for March 5, 2021.

Otezla® ANDA Patent Litigation

Amgen Inc. v. Sandoz Inc., et al.

Beginning in June 2018, Celgene filed 19 separate lawsuits in the U.S. District Court for the District of New Jersey (the New Jersey District Court) against Alkem Laboratories Ltd. (Alkem); Amneal Pharmaceuticals LLC; Annora Pharma Private Ltd. and Hetero USA Inc. (collectively, Hetero); Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. (collectively, Aurobindo); Cipla Limited (Cipla Ltd); DRL; Emcure Pharmaceuticals Ltd. and Heritage Pharmaceuticals Inc. (collectively, Emcure); Glenmark Pharmaceuticals Ltd. (Glenmark); Macleods Pharmaceuticals Ltd. (Macleods); Mankind Pharma Ltd. (Mankind); MSN Laboratories Private Limited; Pharmascience Inc. (Pharmascience); Prinston Pharmaceutical Inc. (Prinston); Sandoz Inc.; Shilpa Medicare Ltd. (Shilpa); Teva Pharmaceuticals USA, Inc. and Actavis LLC (collectively, Actavis); Torrent Pharmaceuticals Ltd. (Torrent); Unichem Laboratories, Ltd. (Unichem); and Zydus Pharmaceuticals (USA) Inc., each for infringement of one or more of the following patents: U.S. Patent Nos. 6,962,940 (the ’940 Patent), 7,208,516 (the ’516 Patent), 7,427,638 (the ’638 Patent), 7,659,302 (the ’302 Patent), 7,893,101 (the ’101 Patent), 8,455,536 (the ’536 Patent), 8,802,717 (the ’717 Patent), 9,018,243 (the ’243 Patent) and 9,872,854 (the ’854 Patent), which are listed in the Orange Book for Otezla®. Each of the defendants is seeking to market a generic version of Otezla® before expiration of the asserted patents. The New Jersey District Court consolidated these 19 lawsuits for discovery and case management purposes into a single case, *Celgene Corp. v. Sandoz Inc., et al.* Each lawsuit seeks an order of the New Jersey District Court making any FDA approval of the respective defendant’s ANDA effective no earlier than the expiration of the applicable patents.

In August 2018, Celgene filed amended complaints against Alkem, Amneal Pharmaceuticals LLC, Aurobindo, Cipla Ltd, DRL, Glenmark, Pharmascience, Sandoz Inc., Actavis, Unichem and Zydus Pharmaceuticals (USA) Inc. additionally asserting U.S. Patent No. 9,724,330 (the ’330 Patent), which is listed in the Orange Book for Otezla®. Between October 15 and November 27, 2018, Celgene filed amended complaints against Alkem, Amneal Pharmaceuticals LLC, Hetero, Aurobindo, Cipla Ltd, DRL, Emcure, Glenmark, Macleods, Mankind, MSN Laboratories Private Limited, Pharmascience, Prinston, Sandoz Inc., Actavis, Torrent, Unichem and Zydus Pharmaceuticals (USA) Inc. additionally asserting U.S. Patent No. 10,092,541 (the ’541 Patent), which is listed in the Orange Book for Otezla®. Between March 1 and April 4, 2019, Celgene filed amended complaints against Hetero, MSN Laboratories Private Limited and Emcure for infringement of one or more of the above-listed patents. On October 1, 2019, Celgene filed an amended complaint against Mankind for infringement of the ’940, ’302, ’536, ’243 and ’330 Patents. On October 8, 2019, Celgene filed a separate lawsuit against Zydus Pharmaceuticals (USA) Inc. in the New Jersey District Court for infringement of U.S. Patent Nos. 8,093,283 (the ’283 Patent) and 8,629,173 (the ’173 Patent), which are not listed in the Orange Book for Otezla®. On December 19, 2019, the New Jersey District Court consolidated this lawsuit for discovery and case management purposes into the existing consolidated case, *Celgene Corp. v. Sandoz Inc., et al*. Each defendant has filed an answer to the above-listed complaints and amended complaints disputing infringement and/or validity of the patents asserted against it. Along with their answers, each of Alkem, Hetero, Cipla Ltd, DRL, Emcure, Glenmark, Macleods, Mankind, Pharmascience, Sandoz Inc., Shilpa, Actavis, Torrent, Unichem and Zydus Pharmaceuticals (USA) Inc. filed declaratory judgment counterclaims asserting that some or all of the patents are not infringed and/or are invalid. In August 2019, based on a joint request by Celgene and Glenmark, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, having made, using, selling, offering to sell, importing, or distributing of Glenmark’s apremilast product during the term of the ’940, ’638, ’302, ’101, ’536, ’243, ’330 and ’541 Patents, unless authorized pursuant to a confidential settlement agreement.

Following Amgen's acquisition of the patents-in-suit and the new drug application for Otezla®, on February 14, 2020, the New Jersey District Court issued an order substituting Amgen for Celgene as plaintiff in the consolidated action and all related actions, terminating Celgene as plaintiff in the consolidated action and all related actions, and amending the case caption in the consolidated action and all related actions to reflect Amgen as the sole plaintiff.

On March 25, 2020, based on a joint request by Amgen and Unichem, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Unichem's apremilast product during the term of the '940, '638, '302, '101, '536, '243, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On April 3, 2020, based on a joint request by Amgen and Hetero, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Hetero's apremilast product during the term of the '940, '516, '638, '302, '101, '536, '717, '243, '330, '854 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On May 28, 2020, based on a joint request by Amgen and Emcure, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Emcure's apremilast product during the term of the '638, '101, '854 and '541 Patents unless authorized pursuant to a confidential settlement agreement. On July 7, 2020, the New Jersey District Court ordered a stipulated dismissal without prejudice of all claims, counterclaims, and affirmative defenses between Amgen and Sandoz Inc. with respect to the '717, '516 and '854 Patents, leaving the '940, '302, '536, '243, '330, '638, '101 and '541 Patents asserted by Amgen against Sandoz Inc. in the litigation. On August 6, 2020, based on a joint request by Amgen and Mankind, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Mankind's apremilast product during the term of the '940, '302, '536, '243, '330, '638, '101 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On August 14, 2020, based on a joint request by Amgen and Macleods, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Macleods' apremilast product during the term of the '638 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On October 7, 2020, based on a joint request by Amgen and Amneal Pharmaceuticals LLC, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Amneal Pharmaceuticals LLC's apremilast product during the term of the '101, '940, '638, '302, '536, '243, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On December 30, 2020, based on a joint request by Amgen and Shilpa, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Shilpa's apremilast product during the term of the '638, '101 and '854 Patents, unless authorized pursuant to a confidential settlement agreement. On January 26, 2021, based on a joint request by Amgen and Actavis, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Actavis' apremilast product during the term of the '940, '516, '638, '302, '536, '717, '330, '854 and '541 Patents, unless authorized pursuant to a confidential settlement agreement.

Trial in the consolidated action against the remaining defendants is scheduled to commence on June 14, 2021.

Sensipar® (cinacalcet) ANDA Patent Litigation

Amgen Inc. v. Amneal Pharmaceuticals LLC, et al. (formerly, Amgen Inc. v. Aurobindo Pharma Ltd. et al.)

Beginning in September 2016, Amgen filed 14 separate lawsuits in the Delaware District Court for infringement of our U.S. Patent No. 9,375,405 (the '405 Patent) against a number of manufacturers of purported generic versions of our Sensipar® product. In February 2017, the Delaware District Court consolidated these 14 lawsuits into a single case, *Amgen Inc. v. Aurobindo Pharma Ltd. et al.* In June 2017, Amgen filed an additional lawsuit in the Delaware District Court for infringement of the '405 Patent which was consolidated into *Amgen Inc. v. Aurobindo Pharma Ltd. et al*. in August 2017. The '405 Patent is entitled "Rapid Dissolution Formulation of a Calcium Receptor-Active Compound" and expires in 2026. All defendants responding to the complaint denied infringement and sought judgment that the '405 Patent is invalid and/or not infringed.

Between September and November of 2017, Amgen filed, and the Delaware District Court signed, stipulated dismissals of the lawsuit against Micro Labs Ltd. and Micro Labs USA, Inc., and the lawsuit against Apotex, as well as consent judgments filed by Amgen and each of (1) Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, Sun); (2) Ajanta Pharma Limited and Ajanta Pharma USA, Inc.; (3) Hetero USA Inc., Hetero Labs Ltd. and Hetero Labs Ltd. Unit V; and (4) Breckenridge. Each consent judgment stipulated to an entry of judgment of infringement and validity of the '405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of or distribution into the United States of the respective defendant's cinacalcet product during the term of the '405 Patent, unless specifically authorized pursuant to the confidential settlement agreement.

In March 2018, the Delaware District Court commenced trial on the infringement claims and defenses in the *Amgen Inc. v. Aurobindo Pharma Ltd. et al.* consolidated lawsuit against the defendants that remained in the lawsuit, collectively consisting of (1) Watson Laboratories, Inc. and Actavis Pharma, Inc. (collectively, Watson); (2) Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); (3) Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, Zydus); and (4) Piramal Healthcare UK Limited (Piramal). Just prior to trial, the Delaware District Court signed consent judgments filed by Amgen and each of Cipla, and Strides Pharma Global Pte Limited and Strides Pharma, Inc. (collectively, Strides), and a consent judgment filed by Amgen and Aurobindo. In each consent judgment, the parties stipulated to an entry of judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of or distribution into the United States of the applicable defendant’s cinacalcet product during the term of the ’405 Patent, unless specifically authorized pursuant to the applicable confidential settlement agreement. Just prior to trial, the Delaware District Court also entered orders dismissing each of DRL and Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan), on stipulations between Amgen and such parties, respectively, subject to the terms of confidential settlement agreements.

In July 2018, the Delaware District Court issued a trial order finding on the infringement claims and defenses in the *Amgen Inc. v. Aurobindo Pharma Ltd. et al.* consolidated lawsuit that Zydus infringes the ’405 Patent and that Amneal, Piramal and Watson do not infringe the ’405 Patent. In August 2018, the Delaware District Court issued an order dismissing, without prejudice, the invalidity counterclaims of Amneal, Piramal and Watson and entered judgment of noninfringement of the ’405 Patent in favor of Amneal, Piramal and Watson. In September 2018, Amgen filed a notice of appeal to the Federal Circuit Court.

In October 2018, the Delaware District Court dismissed, without prejudice, the invalidity counterclaims of Zydus and entered judgment of infringement of the ’405 Patent by Zydus in favor of Amgen, including an order that the effective date of the FDA approval of Zydus’ generic version of Sensipar® shall be no earlier than the expiry date of our ’405 Patent. Also in October 2018, Zydus filed a notice of appeal to the Federal Circuit Court, and the Federal Circuit Court consolidated the appeals of Zydus and Amgen.

In December 2018, the FDA approved Watson’s generic version of Sensipar® and Watson’s parent company, Teva Pharmaceutical Industries Ltd. (Teva), began selling its product at-risk notwithstanding that the appeals were pending at the Federal Circuit Court. On January 2, 2019, Amgen, Watson and Teva entered into a settlement agreement in which Teva agreed to stop selling its generic product until the mid-year 2021 (or earlier under certain circumstances) and to pay Amgen an undisclosed amount. On January 9, 2019, Watson and Amgen filed a motion asking the Delaware District Court to vacate its final judgment of noninfringement as to Watson and to enter a proposed consent judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the making, having made, using, selling, offering to sell, or distributing Watson’s cinacalcet product in the United States or importing Watson’s cinacalcet product into the United States, consistent with the confidential settlement agreement. On January 11, 2019, the Federal Circuit Court stayed the pending appeal by Amgen of the judgment of noninfringement as to Watson in order for the Delaware District Court to rule on the motion of Watson and Amgen. On March 26, 2019, the Delaware District Court denied the joint motion for indicative ruling of Watson and Amgen. On April 10, 2019, Amgen filed an appeal to the Federal Circuit Court and the Federal Circuit Court lifted the stay of Amgen’s appeal of the judgment of noninfringement as to Watson and consolidated it with Amgen’s appeal of the Delaware District Court’s denial of the joint motion for indicative ruling. On September 13, 2019, the Federal Circuit Court denied Amgen’s motion and lifted the stay of the briefing schedule which had been stayed pending disposition of Amgen’s motion to vacate. On July 9, 2020, the Federal Circuit Court granted a motion filed by Amgen and Watson to dismiss Amgen’s appeals of the Delaware District Court’s judgment of noninfringement as to Watson and denial of the joint motion for indicative ruling.

On March 19, 2019, Amgen filed an emergency motion for an injunction pending appeal, seeking an order from the Delaware District Court enjoining defendant Piramal from making, using, selling, offering for sale or importing its generic cinacalcet product. Amgen’s motion follows an announcement that Slate Run Pharmaceuticals LLC (Slate Run), in partnership with Piramal, had begun selling Piramal’s generic cinacalcet product at-risk notwithstanding the appeals pending at the Federal Circuit Court. On April 15, 2019, the Delaware District Court signed an order enjoining Piramal and Slate Run from selling their generic cinacalcet product until certain events occur related to a decision by the Federal Circuit Court on the parties’ appeal. The order has no effect on the product that Piramal and Slate Run had already sold to third parties.

On January 7, 2020, the Federal Circuit Court issued an opinion affirming the judgment of noninfringement with respect to Piramal, affirming the judgment of infringement with respect to Zydus and vacating and remanding to the Delaware District Court for further consideration the judgment of noninfringement with respect to Amneal. On April 22, 2020, the Federal Circuit Court issued a mandate returning the case to the Delaware District Court. On September 8, 2020, the Delaware District Court entered judgment of validity and infringement of the ’405 Patent in the lawsuit filed against Amneal and, except to the extent specifically authorized in a confidential settlement agreement, enjoined Amneal from infringing the ’405 Patent by making, using, selling, offering to sell or importing Amneal’s cinacalcet product during the term of the patent.

A hearing before the Delaware District Court on the request of Piramal to recover damages for being enjoined during the pendency of Amgen's appeal has been rescheduled for March 24, 2021. On October 14, 2020, the Delaware District Court issued an order permitting Slate Run, Piramal's business partner, to intervene in the pending action.

ENBREL Patent Litigation

Immunex Corporation, et al. v. Sandoz Inc., et al.

In February 2016, two affiliates of Amgen Inc., Immunex Corporation and Amgen Manufacturing, Limited (collectively, Amgen), along with Hoffmann-La Roche Inc. (Roche), filed a lawsuit in the New Jersey District Court against Sandoz Inc., Sandoz International GmbH and Sandoz GmbH (collectively, Sandoz). This lawsuit stems from Sandoz's submission of an application for FDA licensure of an etanercept product as biosimilar to Amgen's ENBREL. Amgen and Roche have asserted infringement of five patents: U.S. Patent Nos. 8,063,182 (the '182 Patent), 8,163,522 (the '522 Patent), 7,915,225 (the '225 Patent), 8,119,605 (the '605 Patent) and 8,722,631 (the '631 Patent). By their complaint, Amgen and Roche seek an injunction to prohibit Sandoz from commercializing its biosimilar etanercept product in the United States prior to the expiry of such patents. All Sandoz defendants responded by denying infringement and/or asserting that the patents at issue are invalid. In August 2016, and subject to the terms of a confidential stipulation, the New Jersey District Court entered a preliminary injunction prohibiting Sandoz from making, using, importing, selling or offering for sale Sandoz's etanercept product. Sandoz's Erelzi™, a biosimilar to ENBREL, was approved by the FDA in August 2016.

In September 2018, the New Jersey District Court entered an order that the making, using, offering to sell or selling in the United States or the importation into the United States by Sandoz of Sandoz's biosimilar etanercept product infringes the '182 and '522 Patents and held a bench trial, focusing on Sandoz's challenges to the validity of these patents.

On August 9, 2019, the New Jersey District Court issued its decision upholding the validity of the '182 and '522 Patents. On October 8, 2019, by stipulation of Amgen and Sandoz, the New Jersey District Court entered final judgment and a permanent injunction prohibiting Sandoz from making, using, importing, selling or offering for sale Sandoz's etanercept product, and, on the same day, Sandoz appealed the final judgment to the Federal Circuit Court. Following a motion by Sandoz, the Federal Circuit Court ordered an expedited briefing schedule for the appeal.

On March 4, 2020, the Federal Circuit Court heard oral argument on the appeal. On July 1, 2020, the Federal Circuit Court affirmed the judgment of the New Jersey District Court upholding the validity of the '182 and '522 Patents. On September 29, 2020, the Federal Circuit Court denied the petition for rehearing of Sandoz filed on July 31, 2020. On January 29, 2021, Sandoz filed a petition for certiorari with the U.S. Supreme Court seeking review of the Federal Circuit Court's affirmance of the validity of the '182 and '522 Patents.

Immunex Corporation, et al. v. Samsung Bioepis Co., Ltd.

On April 30, 2019, two affiliates of Amgen Inc., Immunex Corporation and Amgen Manufacturing, Limited (collectively, Amgen), along with Roche, filed a lawsuit in the New Jersey District Court against Samsung Bioepis Co., Ltd. (Bioepis). This lawsuit stems from Bioepis' submission of an application for FDA licensure of an etanercept product as biosimilar to Amgen's ENBREL. Amgen and Roche have asserted infringement of five patents: the '182, '522, '225, '605 and '631 Patents. By their complaint, Amgen and Roche seek an injunction to prohibit Bioepis from commercializing its biosimilar etanercept product in the United States prior to the expiry of such patents. On August 5, 2019, Bioepis responded to the complaint, denying infringement and seeking judgment that the patents-in-suit are invalid, unenforceable and/or not infringed. On January 9, 2020 and subject to the terms of a confidential stipulation and court order of January 6, 2020, the New Jersey District Court entered a consent injunction that prohibits Bioepis from making, using, offering to sell, selling or importing into the United States Bioepis' etanercept product. Amgen and Bioepis entered into an agreement with respect to an injunction regarding etanercept as set out in the New Jersey District Court's order of January 6, 2020. On January 15, 2020, the New Jersey District Court entered an order administratively staying the case pursuant to a joint request of Amgen and Bioepis.

Repatha® Patent Litigation

Amgen Inc., et al. v. Sanofi, et al.

In October 2014, Amgen initiated a series of lawsuits that were consolidated by the Delaware District Court in December 2014 into a single case against Sanofi, Sanofi-Aventis U.S. LLC and Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc. (collectively, Sanofi) and Regeneron Pharmaceuticals, Inc. (Regeneron), addressing seven of our patents: U.S. Patent Nos. 8,563,698; 8,829,165 (the '165 Patent); 8,859,741 (the '741 Patent); 8,871,913; 8,871,914; 8,883,983; and 8,889,834. These patents describe and claim monoclonal antibodies to proprotein convertase subtilisin/kexin type 9 (PCSK9). By its complaints, Amgen seeks an injunction to prevent the infringing manufacture, use and sale of Sanofi and Regeneron's alirocumab, a monoclonal antibody targeting PCSK9. In January 2016, the Delaware District Court granted Amgen's motion to amend the complaint to add its affiliates, Amgen Manufacturing, Limited and Amgen USA Inc., as plaintiffs and to add the allegation that Sanofi and Regeneron's infringement of Amgen's patents is willful.

In February 2016, the Delaware District Court entered a stipulated order finding alirocumab and the drug product containing it, PRALUENT® infringe certain of Amgen's patents, including claims 2, 7, 9, 15, 19 and 29 of the '165 Patent and claim 7 of the '741 Patent. In March 2016, the Delaware District Court entered judgment in favor of Amgen following a five-day jury trial and a unanimous jury verdict that these patent claims are all valid. In January 2017, the Delaware District Court denied Sanofi and Regeneron's post-trial motions seeking a new trial and for judgment as a matter of law, and granted Amgen's motion for a permanent injunction prohibiting the infringing manufacture, use, sale, offer for sale or import of alirocumab in the United States. Sanofi and Regeneron filed an appeal of the judgment and the permanent injunction to the Federal Circuit Court. In February 2017, following a motion by Sanofi and Regeneron, the Federal Circuit Court entered a stay of the permanent injunction during the pendency of the appeal. In October 2017, the Federal Circuit Court reversed in part the judgment of the Delaware District Court and remanded for a new trial two of the patent validity defenses (lack of written description and enablement of the claimed inventions), and affirmed the Delaware District Court's judgment of infringement of claims 2, 7, 9, 15, 19 and 29 of the '165 Patent and claim 7 of the '741 Patent and the third patent validity defense (finding that the claimed inventions were not obvious to a person of ordinary skill in the field of the patents).

In March 2018, the Federal Circuit Court issued a mandate returning the case to the Delaware District Court for a new trial on two of Sanofi and Regeneron's challenges to the validity of our patents (lack of written description and enablement of the claimed inventions) and for further consideration of a permanent injunction. In July 2018, Amgen filed a petition for certiorari with the U.S. Supreme Court seeking review of the Federal Circuit Court's conclusion that the judgment affirming the validity of Amgen's patents was based, in part, on an erroneous application of the law of written description. On January 7, 2019, the U.S. Supreme Court denied Amgen's petition for certiorari. On remand, the Delaware District Court scheduled a new trial on Sanofi and Regeneron's challenges to the validity of our patents based on lack of written description and enablement of the claimed inventions. The Delaware District Court also entered judgment on the pleadings for Sanofi and Regeneron on Amgen's claim of willful infringement.

On February 25, 2019, a jury of the Delaware District Court unanimously upheld the validity of claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent. The jury also found that claims 7 and 15 of the '165 Patent meet the enablement requirement, but are invalid for failure to meet the written description requirement. On March 18, 2019, Sanofi and Regeneron filed post-trial motions seeking to reverse judgment as a matter of law or for a new trial with respect to claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent, and Amgen filed a motion for a permanent injunction. On June 6, 13 and 21, 2019, the Delaware District Court held evidentiary hearings on Amgen's motion for a permanent injunction against PRALUENT®. On August 28, 2019, the Delaware District Court ruled on the post-trial motions, denying Sanofi and Regeneron's request for a new trial and their request to reverse the jury verdict that the '165 Patent and the '741 Patent provide written description support for the claimed inventions. The Delaware District Court also ruled as a matter of law that claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent are invalid for failing to meet the enablement requirement, overturning the jury verdict. On October 23, 2019, Amgen filed a notice of appeal to the Federal Circuit Court. On December 9, 2020, the Federal Circuit Court heard oral argument on the appeal.

Patent Disputes in the International Region

We are involved in and expect future involvement in additional disputes regarding our PCSK9 patents in other jurisdictions and regions. This includes matters filed against us and that we have filed in the United Kingdom, Germany, France, the Netherlands, Italy, Spain and Japan.

In February 2016, the European Patent Office (EPO) granted European Patent No. 2,215,124 (EP 2,215,124) to Amgen. This patent describes and claims monoclonal antibodies to PCSK9 and methods of treatment and Sanofi filed an opposition to the patent in the EPO seeking to invalidate it. In November 2016, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A. and Sanofi Winthrop Industrie S.A. filed a joint opposition against Amgen's patent, and each of Eli Lilly and Company, Regeneron and Strawman Ltd. also filed oppositions to Amgen's patent. In November 2018, the EPO confirmed the validity of Amgen's EP 2,215,124, which was appealed to the Technical Board of Appeal (TBA). On October 29, 2020, the TBA upheld the validity of certain claims, including claims that protect Repatha®, but ruled that broader claims encompassing PRALUENT® were invalid. As a result of the TBA's decision, national litigations regarding PRALUENT® in Europe are in the process of being resolved.

On April 24, 2020, the Supreme Court of Japan declined to hear Sanofi K.K.'s appeals making final the Japanese High Court's decisions that PRALUENT® infringes Amgen's valid patent rights in Japan. On June 24, 2020, Amgen filed written answers to the invalidity trials initiated by Regeneron on February 12, 2020 before the Japan Patent Office seeking to invalidate Amgen's Japanese patents that were previously held infringed by PRALUENT® and valid over challenges filed by Sanofi K.K. Damages proceedings against Sanofi K.K. are ongoing before the Tokyo District Court, where Sanofi K.K. has initiated new validity challenges to Amgen patents in Japan.

NEUPOGEN® (filgrastim)/Neulasta® Patent Litigation

Amgen Inc., et al. v. Pfizer Inc. et al.

In July 2018, Amgen Inc. and its wholly owned subsidiary, Amgen Manufacturing, Limited (collectively, Amgen), filed a lawsuit in the Delaware District Court against Pfizer Inc. and Hospira Inc. (collectively, Pfizer). This lawsuit stems from Pfizer's submission of an application for FDA licensure of a filgrastim product as biosimilar to Amgen's NEUPOGEN®. Amgen has asserted infringement of U.S. Patent No. 9,643,997 (the '997 Patent) and seeks, among other remedies, injunctive relief to prohibit Pfizer from infringing the '997 Patent. In July 2018, the FDA approved Pfizer's NIVESTYM™, a biosimilar to NEUPOGEN®, which was subsequently launched in October 2018. In August 2018, Pfizer answered the complaint and counterclaimed seeking a declaration that Pfizer does not infringe Amgen's '997 Patent and that the patent is invalid.

On March 22, 2019, Amgen filed an amended complaint against Pfizer in the Delaware District Court narrowing the patent claims at issue in the infringement dispute and adding a request for damages. On April 11, 2019, Pfizer answered Amgen's amended complaint including counterclaims seeking declaratory judgments of noninfringement and invalidity. On February 18, 2020, the Delaware District Court entered an amended scheduling order moving the trial on the infringement of our '997 Patent to May 17, 2021, to enable Amgen to seek additional discovery into Pfizer's invalidity defenses.

On April 24, 2020, Amgen filed a separate lawsuit in the Delaware District Court against Pfizer for infringement of U.S. Patent No. 10,577,392 (the '392 Patent) and seeks, among other remedies, damages and injunctive relief to prohibit Pfizer from infringing the '392 Patent by the manufacture, import and sale of Pfizer's NIVESTYM™. On January 7, 2021, the Delaware District Court granted Pfizer's request to stay the patent infringement lawsuit on the '392 Patent until the co-pending patent infringement lawsuit on the '997 Patent is resolved.

Amgen Inc., et al. v. Hospira Inc. et al.

On February 11, 2020, Amgen Inc. and its wholly owned subsidiary, Amgen Manufacturing, Limited (collectively, Amgen), filed a lawsuit in the Delaware District Court against Pfizer. This lawsuit stems from Pfizer's submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen's Neulasta®. Amgen has asserted infringement of U.S. Patent No. 8,273,707 (the '707 Patent) and seeks, among other remedies, injunctive relief to prohibit Pfizer from infringing the '707 Patent. On March 4, 2020, Pfizer filed a motion requesting the Delaware District Court to dismiss the complaint by Amgen alleging noninfringement of the '707 Patent. In June 2020, the FDA approved Pfizer's NYVEPRIA™, a biosimilar to Amgen's Neulasta®.

Patent Trial and Appeal Board (PTAB) Challenge

Lupin PTAB Challenge

On December 15, 2020, Lupin Limited (Lupin) filed a petition to institute inter parties review (IPR) proceeding at the U.S. Patent and Trademark Office (USPTO) of U.S. Patent No. 9,856,287 (the '287 Patent) challenging claims

of the ’287 Patent as unpatentable. Amgen’ s preliminary response is due on April 14, 2021 and the PTAB will then have no more than three months to decide whether to institute a proceeding.

Apotex PTAB Challenge

In February 2017, the PTAB of the USPTO granted Apotex's petition to institute IPR proceeding of U.S. Patent No. 8,952,138 (the '138 Patent), challenging claims of the '138 Patent as unpatentable. In May 2017, Amgen filed its response. In February 2018, the PTAB issued a final decision holding all but one claim of the '138 Patent as unpatentable and Apotex filed a request for rehearing in March 2018.

On May 20, 2019, the PTAB issued a decision denying Apotex's request for rehearing on the PTAB's finding and *sua sponte* amending the final decision with a finding that the one remaining claim in Amgen's '138 Patent is unpatentable. On July 22, 2019, Amgen filed a notice of appeal to the Federal Circuit Court with respect to all claims held to be unpatentable. On August 5, 2019, Apotex provided notice that it would not participate in the appeal. On September 16, 2019, the USPTO filed a notice of intervention on the appeal. On March 24, 2020, the Federal Circuit Court vacated the decision by the PTAB and remanded the case to the PTAB for proceeding consistent with the Federal Circuit Court's decision in *Arthrex Inc. v. Smith & Nephew, Inc*., 941 F.3d 1320 (Fed. Cir. 2019).

On July 14, 2020, Amgen and Apotex filed a joint motion to terminate the IPR proceedings stating that there is no current dispute between the parties with respect to the '138 Patent. On July 29, 2020, the U.S. government filed a petition for writ of certiorari with respect to the cases that the Federal Circuit Court remanded to the PTAB, including the case regarding the '138 Patent, for proceedings consistent with its decision in *Arthrex Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), requesting that such remanded cases be held pending the U.S. Supreme Court's disposition of the petition for writ of certiorari in *United States v. Arthrex, Inc.*, No. 19-1434. On August 25, 2020, Amgen filed its response to the U.S. government's petition for writ of certiorari indicating that Amgen did not intend to respond unless requested by the U.S. Supreme Court.

Breach of Contract Action

Novartis Pharma AG v. Amgen Inc.

On April 4, 2019, Amgen filed a lawsuit in the U.S. District Court for the Southern District of New York (the New York Southern District Court) against Novartis Pharma AG (Novartis) seeking a declaratory judgment that Novartis materially breached two collaboration agreements Amgen and Novartis entered into in 2015 and 2017 (the 2015 Agreement and the 2017 Agreement, respectively) related to the development and commercialization of Aimovig® due to Novartis' affiliate Sandoz GmbH entering into a contract manufacturing agreement with Alder BioPharmaceuticals, Inc. (Alder) related to eptinezumab, an expected direct competitor to Aimovig® and entrant in the calcitonin gene-related peptide (CGRP)-related migraine therapy market. Amgen seeks to terminate its collaboration agreements with Novartis and also seeks damages from Novartis for breach of contract and negligent misrepresentation. Also on April 4, 2019, Novartis initiated a separate lawsuit against Amgen in the same court seeking declaratory judgment that Novartis, alternatively, did not materially breach the collaboration agreements or, even if it did breach the collaboration agreements, such breach was not material and has been cured, and that Amgen may not terminate the collaboration agreements. On April 8, 2019, Amgen answered Novartis' complaint and filed counterclaims seeking a declaratory judgment that Novartis materially breached the collaboration agreements due to its affiliate Sandoz GmbH entering into the contract manufacturing agreement with Alder. In its counterclaim, Amgen seeks to terminate its collaboration agreements with Novartis and also seeks damages from Novartis for breach of contract and negligent misrepresentation. On July 16, 2019, Novartis filed an amended complaint adding a claim for breach of contract alleging Novartis is owed amounts associated with 2018 budget overruns and Amgen responded with a counterclaim alleging additional breaches by Novartis of the collaboration agreements. On September 17, 2019 and October 8, 2019, Novartis and Amgen, respectively, each filed its motion for judgment on the pleadings. On February 3, 2020, Amgen was granted leave to file its amended counterclaims. On February 4, 2020, Amgen filed its amended answer to Novartis' first amended complaint and second amended counterclaims for affirmative relief to add a fraudulent inducement claim. On February 18, 2020, Novartis filed its answer and affirmative defenses to Amgen's second amended counterclaims.

On June 9, 2020, the New York Southern District Court entered an order granting Novartis' motion for judgment on the pleadings that Novartis did not breach the 2017 Agreement, and denying Amgen's motions for judgment on the pleadings seeking dismissal of Novartis' amended complaint that Novartis did not breach the 2015 Agreement or the 2017 Agreement, and Novartis timely cured any breach. On June 23, 2020, Amgen filed a motion for clarification and/or reconsideration of the June 9, 2020 order, which was denied on September 14, 2020.

Antitrust Class Action

Sensipar® Antitrust Class Actions

From February to April 2019, four plaintiffs filed putative class action lawsuits against Amgen and various entities affiliated with Teva alleging anticompetitive conduct in connection with settlements between Amgen and manufacturers of generic cinacalcet product. Two of those actions were brought in the Delaware District Court, captioned *UFCW Local 1500 Welfare Fund v. Amgen Inc., et al.* (February 21, 2019) (Local 1500) and *Cesar Castillo, Inc. v. Amgen Inc., et al.* (February 26, 2019) (Castillo). The third action was brought in the New Jersey District Court, captioned *Teamsters Local 237 Welfare Fund, et al. v. Amgen Inc., et al.* (March 14, 2019) (Local 237) and the fourth action was brought in the U.S. District Court for the Eastern District of Pennsylvania (the Eastern Pennsylvania District Court), captioned *KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. v. Amgen Inc., et al* (April 10, 2019) (KPH). Each of the lawsuits is brought on behalf of a putative class of direct or indirect purchasers of Sensipar® and alleges that the plaintiffs have overpaid for Sensipar® as a result of Amgen's conduct that allegedly improperly delayed market entry by manufacturers of generic cinacalcet products. The lawsuits focus predominantly on the settlement among Amgen, Watson and Teva of the parties' patent infringement litigation. Each of the lawsuits seeks, among other things, treble damages, equitable relief and attorneys' fees and costs. On April 10, 2019, the plaintiff in the KPH lawsuit filed a motion seeking to have the four lawsuits consolidated and designated as a multidistrict litigation (MDL) in the Eastern Pennsylvania District Court, and the plaintiff in the Local 1500 lawsuit filed a motion seeking to have the four lawsuits, along with *Cipla Ltd. v. Amgen Inc.*, consolidated and designated as a MDL in the Delaware District Court.

On July 31, 2019, the MDL panel entered an order consolidating in the Delaware District Court the four class action lawsuits. On September 13, 2019, the plaintiffs filed amended complaints, and on October 15, 2019, Amgen filed its motion to dismiss both the direct purchaser plaintiffs' consolidated class action complaint and the indirect purchaser end payor plaintiffs' complaint. On December 6, 2019, the plaintiffs responded to Amgen's motion to dismiss and, on January 10, 2020, Amgen filed its response. On February 6, 2020, the motions in the class action lawsuits were transferred to the U.S. Magistrate Judge for the District of Delaware (Magistrate Judge) for a recommendation. The MDL panel certified its conditional transfer order on February 6, 2020 transferring the additional class action lawsuit brought in the U.S. District Court for the Southern District of Florida, captioned *MSP Recovery Claims v. Amgen Inc., et al.*, to the Delaware District Court.

On July 22, 2020, the Magistrate Judge issued a recommendation to the Delaware District Court that the claims against Amgen be dismissed but leave be given to plaintiffs to amend their complaints. On August 5, 2020, the plaintiffs filed objections to the Magistrate Judge's report and recommendation. On August 19, 2020, Amgen filed a response to the plaintiffs' objections. On November 30, 2020, the District Court adopted the Magistrate Judge's recommendation in part and denied it in part, denying Amgen's motion to dismiss on the grounds that plaintiffs adequately alleged reverse payment claims but granted Amgen's motion to dismiss with respect to the other Federal antitrust claims. On December 23, 2020, Teva, Watson and Actavis filed a motion for interlocutory appeal and for a stay pending appeal and Amgen filed its joinder (the 1292 Motion). On January 5, 2021, a joint status report was filed advising the Delaware District Court that the defendants are still considering whether to withdraw the 1292 Motion and plaintiffs' offer to stay discovery, pending further rulings on motions to dismiss the amended complaints. On January 19, 2021, a joint status report was filed pursuant to the Delaware District Court's January 6, 2021 order along with a stipulation to defer the 1292 Motion until after rulings on the amended complaints.

Humira® Biosimilar Antitrust Class Actions

From March to May 2019, twelve purported class actions against Amgen, along with AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively, AbbVie), were filed in the U.S. District Court for the Northern District of Illinois (the Illinois Northern District Court). The cases are captioned: *UFCW Local 1500 Welfare Fund v. AbbVie Inc., et al.* (March 18, 2019) (Local 1500); *Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund v. AbbVie Inc., et al.* (March 20, 2019); *Mayor and City Council of Baltimore v. AbbVie Inc., et al.* (March 22, 2019); *Pipe Trades Services MN Welfare Fund v. AbbVie Inc., et al.* (March 29, 2019); *St. Paul Electrical Workers' Health Plan v. AbbVie Inc., et al.* (March 29, 2019); *Welfare Plan of the International Union of Operating Engineers Locals 137, 137A, 137B, 137C and 137R v. AbbVie Inc., et al.* (April 1, 2019); *Law Enforcement Health Benefits, Inc. v. AbbVie, Inc., et al.* (April 9, 2019) (Law Enforcement); *Kentucky Laborers District Council Health and Welfare Fund v. AbbVie, Inc., et al.* (April 16, 2019); *Sheet Metal Workers' Local Union No. 28 Welfare Fund v. AbbVie, Inc., et al.* (April 19, 2019) (Sheet Metal Workers'); *Locals 302 & 612 of The International Union of Operating Engineers-Employers Construction Industry Health And Security Trust Fund v. AbbVie Inc., et al.* (April 25, 2019) (Construction Industry);

Louisiana Health Service & Indemnity Co., d/b/a Blue Cross and Blue Shield of Louisiana and HMO Louisiana, Inc. v. AbbVie Inc., *et al.* (April 30, 2019) (Louisiana Health); and *Cleveland Bakers and Teamsters Health and Welfare Fund v. AbbVie Inc., et al.* (May 10, 2019) (Cleveland Bakers) (collectively, Humira® Antitrust Class Actions).

In each of the Humira® Antitrust Class Actions, the plaintiffs bring federal antitrust claims along with various state law claims under common law and antitrust, consumer protection and unfair competition statutes. In each case, the plaintiffs specifically allege that AbbVie has unlawfully monopolized the alleged market for Humira® and biosimilars of Humira®, including by creating an allegedly unlawful so-called patent thicket around Humira®. In the Local 1500, Sheet Metal Workers' and Construction Industry cases, the plaintiffs further allege that AbbVie entered into allegedly unlawful market division agreements with Amgen and other companies that had developed Humira® biosimilars, including Bioepis, Mylan, Sandoz, Inc., Fresenius Kabi USA, LLC, Pfizer Inc. and Momenta Pharmaceuticals, Inc., in connection with the settlement of patent litigation relating to Humira®, whereby Amgen and the other defendants that have developed Humira® biosimilars were permitted to market those products in Europe as early as October 2018, while remaining off the market in the United States until 2023. In each of the Humira® Antitrust Class Actions other than the Local 1500 and Construction Industry cases, the plaintiffs allege that AbbVie and Amgen entered into an allegedly unlawful settlement agreement under which Amgen allegedly agreed to delay its entry into the U.S. market with AMGEVITA™ (adalimumab), its Humira® biosimilar, in exchange for an alleged promise of exclusivity as the sole Humira® biosimilar in that market for five months, beginning in January 2023. In each of the Humira® Antitrust Class Actions, plaintiffs seek injunctive relief, treble damages and attorney's fees on behalf of a putative class of third-party payers and/or consumers that have indirectly purchased, paid for or provided reimbursement for Humira® in the United States. Defendants' responses to the first six complaints were stayed by the court. On June 4, 2019, the Illinois Northern District Court entered an order consolidating the twelve purported class action cases for pre-trial purposes.

On August 9, 2019, the plaintiffs filed their consolidated complaint, naming as defendants Amgen, along with AbbVie, Bioepis, Sandoz, Inc. and Fresenius Kabi USA LLC. On October 11, 2019, the defendants filed a joint motion to dismiss the consolidated complaint (as well as brief individual motions), challenging the legal sufficiency of the plaintiffs' allegations to state any claim for relief under the law. On November 19, 2019, plaintiffs filed their opposition to the motion to dismiss. On December 20, 2019, defendants filed their reply in support of the motion to dismiss. On June 8, 2020, the Illinois Northern District Court issued an order granting the motion by the defendants to dismiss the consolidated class action complaint. On June 29, 2020, the plaintiffs filed a status report asking the Illinois Northern District Court to convert the dismissal to one with prejudice. On June 30, 2020, the Illinois Northern District Court granted the motion. On July 28, 2020, the plaintiffs filed a notice of appeal. On October 5, 2020, the plaintiffs-appellants filed their opening brief to the U.S. Court of Appeals for the Seventh Circuit. Plaintiffs-appellants amicus briefs were filed in October 2020, including one by the Federal Trade Commission and one on behalf of 20 states, each filed on October 13, 2020. On December 21, 2020, the defendants-appellees filed their opposition brief. Defendants-appellees amicus briefs, including one by the Department of Justice, were filed on December 28, 2020. The plaintiffs-appellants' reply brief was filed on February 1, 2021, and oral argument has been scheduled for February 25, 2021.

Commitments – U.S. repatriation tax

Under the 2017 Tax Act, we elected to pay in eight annual installments the repatriation tax related primarily to prior indefinitely invested earnings of our foreign operations. The following table summarizes the remaining scheduled repatriation tax payments as of December 31, 2020 (in millions):

2021	$
2022	
2023	
2024	
2025	
Total remaining U.S. repatriation tax commitments	$

20. Quarterly financial data (unaudited)

The following tables summarize the Company's unaudited financial data on a quarterly basis. The sum of the quarterly earnings per-share amounts may not equal the amount reported for the full year because per-share amounts are computed independently for each quarter and for the full year based on respective weighted-average shares outstanding and dilutive securities.

Quarterly financial data is summarized as follows (in millions, except per-share data):

	2020 Quarters ended			
	December 31	September 30	June 30	March 31
Product sales	$ 6,334	$ 6,104	$ 5,908	$ 5,894
Gross profit from product sales	$ 4,737	$ 4,543	$ 4,420	$ 4,381
Net income	$ 1,615	$ 2,021	$ 1,803	$ 1,825
Earnings per share:				
Basic	$ 2.78	$ 3.45	$ 3.07	$ 3.09
Diluted	$ 2.76	$ 3.43	$ 3.05	$ 3.07

	2019 Quarters ended			
	December 31	September 30	June 30	March 31
Product sales	$ 5,881	$ 5,463	$ 5,574	$ 5,286
Gross profit from product sales	$ 4,628	$ 4,427	$ 4,562	$ 4,231
Net income	$ 1,703	$ 1,968	$ 2,179	$ 1,992
Earnings per share:				
Basic	$ 2.87	$ 3.29	$ 3.59	$ 3.20
Diluted	$ 2.85	$ 3.27	$ 3.57	$ 3.18

SCHEDULE II

AMGEN INC.

VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2020, 2019 and 2018

(In millions)

Allowance for doubtful accounts	Balance at beginning of period	Additions charged to costs and expenses	Other additions	Deductions	Balance at end of period
Year ended December 31, 2020	$ 26	$ 8	$ —	$ 2	$ 32
Year ended December 31, 2019	$ 48	$ —	$ —	$ 22	$ 26
Year ended December 31, 2018	$ 51	$ 1	$ —	$ 4	$ 48

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**95-3540776**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive	
Thousand Oaks	
California	**91320-1799**
(Address of principal executive offices)	(Zip Code)

(805) 447-1000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol (s)	Name of each exchange on which registered

Common stock, $0.0001 par value	**AMGN**	**The NASDAQ Global Select Market**
1.250% Senior Notes Due 2022	**AMGN22**	**New York Stock Exchange**
2.00% Senior Notes Due 2026	**AMGN26**	**New York Stock Exchange**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company	Emerging growth company
☒	☐	☐	☐	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $110,809,019,075 as of June 30, 2019.[(A)]

(A) Excludes 744,928 shares of common stock held by directors and executive officers, and any stockholders whose ownership exceeds ten percent of the shares outstanding, at June 30, 2019. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

589,806,819

(Number of shares of common stock outstanding as of February 6, 2020)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2020 Annual Meeting of Stockholders to be held May 19, 2020, are incorporated by reference into Part III of this annual report.

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PART I

Item 1. BUSINESS

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen was incorporated in California in 1980 and became a Delaware corporation in 1987. We have a presence in approximately 100 countries worldwide. Amgen operates in one business segment: human therapeutics.

Significant Developments

Following is a summary of significant developments affecting our business that have occurred and that we have reported since the filing of our Annual Report on Form 10-K for the year ended December 31, 2018.

Products/Pipeline

Oncology/Hematology

KANJINTI™ (trastuzumab-anns)*

- In June 2019, the U.S. Food and Drug Administration (FDA) approved KANJINTI™ for all approved indications of the reference product Herceptin® (trastuzumab) for the treatment of HER2-overexpressing adjuvant and metastatic breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. In July 2019, we and Allergan plc (Allergan) launched KANJINTI™ in the United States.

For a discussion of litigation related to KANJINTI™, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

KYPROLIS® (carfilzomib)

- In September 2019, we announced that the phase 3 CANDOR (Carfilzomib, Daratumumab and Dexamethasone for Patients With Relapsed and/or Refractory Multiple Myeloma) study evaluating KYPROLIS® in combination with dexamethasone and DARZALEX® (daratumumab) compared to KYPROLIS® and dexamethasone alone in patients with relapsed multiple myeloma met its primary endpoint of progression-free survival (PFS).

- In January 2020, a supplemental New Drug Application (sNDA) was submitted to the FDA to expand the Prescribing Information to include KYPROLIS® in combination with dexamethasone and DARZALEX® for patients with relapsed or refractory multiple myeloma based on data from the phase 3 CANDOR study.

- In January 2020, our Marketing Authorization Application (MAA) was accepted by the China National Medical Products Administration for the use of KYPROLIS® and dexamethasone for the treatment of relapsed or refractory multiple myeloma.

MVASI™ (bevacizumab-awwb)*

- In July 2019, we and Allergan launched MVASI™ in the United States.

For a discussion of litigation related to MVASI™, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

* Registered in the United States.

Collaboration with BeiGene, Ltd.

- In January 2020, we entered into a strategic collaboration with BeiGene, Ltd. (BeiGene) to support our oncology pipeline and expand our oncology presence in China. As part of the agreement we acquired a 20.5% stake in BeiGene for $2.8 billion in cash.

AMG 510

- In October 2019, the FDA granted AMG 510 fast track designation for the treatment of patients with previously treated metastatic non-small cell lung cancer (NSCLC) with Kirsten rat sarcoma viral oncogene homolog (KRAS) G12C mutation. AMG 510 is a small molecule inhibitor of KRAS G12C.

ABP 798 (biosimilar rituximab)

- In August 2019, we and Allergan announced positive top-line results from a comparative clinical study evaluating the efficacy and safety of ABP 798, a biosimilar candidate to Rituxan® (rituximab), compared to Rituxan® in patients with CD20-positive B-cell non-Hodgkin's lymphoma. The primary endpoint, an assessment of overall response rate by week 28, was within the prespecified margin for ABP 798 compared to Rituxan®, showing clinical equivalence. Safety and immunogenicity of ABP 798 were comparable to Rituxan®.

- In December 2019, we and Allergan submitted a Biologics License Application (BLA) to the FDA for ABP 798.

Cardiovascular

Repatha® (evolocumab)

- In August 2019, the U.S. District Court for the District of Delaware overturned a unanimous jury verdict upholding the validity of two of our patents related to proprotein convertase subtilisin/kexin type 9 (PCSK9) antibodies in our infringement action against Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC and Regeneron Pharmaceuticals, Inc. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Inflammation

AVSOLA™ (infliximab-axxq/formerly ABP 710)

- In December 2019, the FDA approved AVSOLA™ for all approved indications of the reference product REMICADE® (infliximab).

Enbrel® (etanercept)

- In August 2019, the U.S. District Court for the District of New Jersey ruled in Amgen's favor on validity of the two patents that describe and claim ENBREL and methods for making it. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Acquisition of Otezla® (apremilast)

- In November 2019, we completed our acquisition of the worldwide rights to Otezla®, the only oral, non-biologic treatment for psoriasis and psoriatic arthritis from Celgene Corporation (Celgene). Otezla®, along with certain related assets and liabilities, was acquired for $13.4 billion in cash.

Bone health

EVENITY® (romosozumab-aqqg)

- In April 2019, the FDA approved EVENITY® for the treatment of osteoporosis in postmenopausal women at high risk for fracture.

- In December 2019, the European Commission (EC) granted marketing authorization for EVENITY® for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture.

Neuroscience

AMG 520/CNP520

- In July 2019, we and Novartis AG (Novartis) discontinued investigating AMG 520/CNP520, a small molecule inhibitor of beta-site amyloid precursor protein-cleaving enzyme-1 (BACE), for the prevention of Alzheimer's disease.

Marketing, Distribution and Selected Marketed Products

The largest concentration of our sales and marketing forces is based in the United States and Europe. In addition, we continue to expand the commercialization and marketing of our products into other geographic territories, including parts of Latin America, the Middle East and Asia. This expansion is occurring by establishing our own affiliates, by acquiring existing third-party businesses or product rights or by partnering with third parties. Whether we use our own sales and marketing forces or a third party's varies across these markets. Such use typically depends on several factors, including the nature of entry into the new market, the size of an opportunity and operational capabilities. Together with our partners, we market our products to healthcare providers, including physicians or their clinics, dialysis centers, hospitals and pharmacies.

In the United States, we sell primarily to pharmaceutical wholesale distributors, which are the principal means of distributing our products to healthcare providers. We also market certain products through direct-to-consumer channels, including print, television and online media. For further discussion, see Government Regulation—Regulation in the United States—Regulation of Product Marketing and Promotion. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country.

Our product sales to three large wholesalers, AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc., each individually accounted for more than 10% of total revenues for each of the years 2019, 2018 and 2017. On a combined basis, these wholesalers accounted for 81%, 84% and 81% of worldwide gross revenues for 2019, 2018 and 2017, respectively. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

Our products are marketed around the world, with the United States being our largest market. The following chart shows our product sales by principal product and by geography for the years 2019, 2018 and 2017.

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Enbrel® (etanercept)

We market ENBREL, a tumor necrosis factor blocker, primarily in the United States. ENBREL was launched in 1998 and is used primarily in indications for the treatment of adult patients with moderately to severely active rheumatoid arthritis, patients with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and patients with active psoriatic arthritis.

Neulasta® (pegfilgrastim)

We market Neulasta®, a pegylated protein based on the filgrastim molecule, primarily in the United States and Europe. Neulasta® was launched in 2002 and is used primarily in the indication to help reduce the chance of infection due to a low white blood cell count in patients with certain types of cancer (nonmyeloid) who receive anticancer medicines (chemotherapy) that can cause fever and a low blood cell count. In 2015, the Neulasta® Onpro® kit became available in the United States. The Neulasta® Onpro® kit provides physicians the opportunity to initiate the administration of Neulasta® on the same day as chemotherapy, with drug delivery of the recommended dose of Neulasta® at home the day after chemotherapy, thereby saving patients a trip back to the doctor.

Prolia® (denosumab)

We market Prolia® primarily in the United States and Europe. Prolia® contains the same active ingredient as XGEVA® (denosumab) but is approved for different indications, patient populations, doses and frequencies of administration. Prolia® was launched in the United States and Europe in 2010. In the United States, it is used primarily in the indication for the treatment of postmenopausal women with osteoporosis at high risk of fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In Europe, Prolia® is used primarily for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

XGEVA®

We market XGEVA® primarily in the United States and Europe. XGEVA® was launched in the United States in 2010 and is now used primarily in the indication for the prevention of skeletal-related events (SREs) (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumors and multiple myeloma. XGEVA® was launched in Europe in 2011 and is used primarily in the indication for the prevention of SREs in patients with bone metastases from solid tumors. It was approved in January 2018 in the United States and in April 2018 in Europe for the prevention of SREs in patients with multiple myeloma.

Aranesp® (darbepoetin alfa)

We market Aranesp® primarily in the United States and Europe. It was launched in 2001 and is indicated to treat a lower-than-normal number of red blood cells (anemia) caused by chronic kidney disease (CKD) (in both patients on dialysis and patients not on dialysis). Aranesp® is also indicated for the treatment of anemia due to concomitant myelosuppressive chemotherapy in certain patients with nonmyeloid malignancies and when chemotherapy will be used for at least two months after starting Aranesp®.

KYPROLIS® (carfilzomib)

We market KYPROLIS® primarily in the United States and Europe. KYPROLIS® was launched in 2012 and is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. It is also approved as a single agent for patients with relapsed or refractory multiple myeloma who have received one or more previous therapies. In September 2019, the CANDOR phase 3 study of KYPROLIS® in combination with dexamethasone and DARZALEX® met its primary endpoint of PFS in patients with relapsed or refractory multiple myeloma. FDA approval of KYPROLIS® in combination with dexamethasone and DARZALEX® is expected in 2020.

EPOGEN® (epoetin alfa)

We market EPOGEN® in the United States for dialysis patients. EPOGEN® was launched in 1989, and we market it for the indication to treat anemia caused by CKD in patients on dialysis in order to lessen the need for red blood cell transfusions. The majority of our sales are to a large dialysis provider.

Sensipar®/Mimpara® (cinacalcet)

We market cinacalcet as Sensipar® primarily in the United States and as Mimpara® primarily in Europe. It was launched in 2004 and is used primarily in the indication for the treatment of secondary hyperparathyroidism in adult patients with CKD who are on dialysis.

Other Marketed Products

We also market a number of other products in various markets worldwide, including Nplate® (romiplostim), Vectibix® (panitumumab), Repatha® (evolocumab), Parsabiv® (etelcalcetide), BLINCYTO® (blinatumomab), Aimovig® (erenumab-aooe), NEUPOGEN® (filgrastim), Otezla® (apremilast), AMGEVITA™ (adalimumab), KANJINTI™ (trastuzumab), EVENITY® (romosozumab-aqqg), IMLYGIC® (talimogene laherparepvec), MVASI™ (bevacizumab-awwb) and Corlanor® (ivabradine).

Otezla®

In November 2019, we began to market Otezla® upon the closing of our acquisition. Otezla® is used primarily for the treatment of patients with moderate-to-severe plaque psoriasis for whom phototherapy or systemic therapy is appropriate.

Patents

The following table lists our outstanding material patents for the indicated product by territory, general subject matter and latest expiry date. Certain of the European patents are the subjects of supplemental protection certificates that provide additional protection for the products in certain European countries beyond the dates listed in the table. See footnotes to the patent table below.

One or more patents with the same or earlier expiry dates may fall under the same general subject matter and are not listed separately.

Product	Territory	General subject matter	Expiration
Enbrel® (etanercept)	U.S.	Methods of treatment using aqueous formulations	6/8/2023
	U.S.	Formulations	10/19/2037
	U.S.	Fusion protein and pharmaceutical compositions	11/22/2028
	U.S.	DNA encoding fusion protein and methods of making fusion protein	4/24/2029
Prolia®/XGEVA® (denosumab)	U.S.	RANKL antibodies	9/17/2021
	U.S.	Methods of treatment	6/25/2022
	U.S.	Nucleic acids encoding RANKL antibodies and methods of producing RANKL antibodies	11/30/2023
	U.S.	RANKL antibodies, including sequences	2/19/2025
	Europe	RANKL antibodies, including epitope binding	2/23/2021
	Europe	RANKL antibodies, including sequences(1)	6/25/2022
Aranesp® (darbepoetin alfa)	U.S.	Glycosylation analogs of erythropoietin proteins	5/15/2024
Sensipar®/ Mimpara® (cinacalcet)	U.S.	Formulation	9/22/2026
	Europe	Calcium receptor-active molecules(1)	10/23/2015
	Europe	Formulation	9/10/2024
KYPROLIS® (carfilzomib)	U.S.	Compositions and compounds	12/7/2027
	U.S.	Methods of treatment	4/14/2025
	U.S.	Methods of making	5/8/2033
	Europe	Compositions, compounds and methods of treatment(1)	8/8/2025
Nplate® (romiplostim)	U.S.	Thrombopoietic compounds	1/19/2022
	U.S.	Formulation	2/12/2028
	Europe	Thrombopoietic compounds(1)	10/22/2019
	Europe	Formulation	4/20/2027
Vectibix® (panitumumab)	U.S.	Human monoclonal antibodies to epidermal growth factor receptor	4/8/2020
	Europe	Human monoclonal antibodies to epidermal growth factor receptor(1)	5/5/2018
Repatha® (evolocumab)	U.S.	Antibodies(2)	10/25/2029
	U.S.	Methods of treatment	10/8/2030
	Europe	Compositions(1)	8/22/2028
	Europe	Methods of treatment	5/10/2032
Parsabiv® (etelcalcetide)	U.S.	Compound and pharmaceutical composition(2)	7/29/2030
	U.S.	Formulation	6/27/2034
	U.S.	Methods of making	8/9/2035
	Europe	Compound and pharmaceutical composition(1)	7/29/2030
	Europe	Formulation	6/27/2034
BLINCYTO® (blinatumomab)	U.S.	Bifunctional polypeptides	4/23/2023
	U.S.	Method of administration	9/28/2027
	Europe	Bifunctional polypeptides(1)	11/26/2024
	Europe	Method of administration	11/6/2029
Aimovig® (erenumab-aooe)	U.S.	CGRP receptor antibodies(2)	11/9/2031
	U.S.	Methods of treatment	4/22/2036
	Europe	CGRP receptor antibodies(1)	12/18/2029
	Europe	Methods of treatment	8/10/2035
IMLYGIC® (talimogene laherparepvec)	U.S.	Compositions	11/23/2025
	U.S.	Method of treatment	3/27/2022
	Europe	Composition and uses(1)	3/27/2022
Corlanor® (ivabradine)	U.S.	Crystalline forms	2/22/2026
EVENITY® (romosozumab-aqqg)	U.S.	Antibodies(2)	4/25/2026
	U.S.	Methods of treatment(2)	1/11/2029

	U.S.	Formulation and methods of using formulation	5/11/2031
	Europe	Antibodies	4/28/2026
	Europe	Methods of treatment	4/18/2032
	Europe	Formulation and methods of using formulation	5/11/2031
Otezla® (apremilast)	U.S.	Compositions and compounds	2/16/2028
	U.S.	Crystalline form	12/9/2023
	U.S.	Methods of treatment	5/29/2034
	Europe	Compositions, compounds and methods of treatment[1]	3/20/2023

CGRP = calcitonin gene-related peptide, RANKL = receptor activator of nuclear factor kappa-B ligand

(1) A European patent with this subject matter may also be entitled to supplemental protection in one or more countries in Europe, and the length of any such extension will vary by country. For example, supplementary protection certificates have been issued related to the indicated products for patents in at least the following countries:

- denosumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2025
- cinacalcet — France, Germany, Italy, Spain and the United Kingdom, expiring in 2020
- carfilzomib — France, Germany, Italy and Spain, expiring in 2030
- romiplostim — France, Germany, Italy, Spain and the United Kingdom, expiring in 2024
- panitumumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2022
- evolocumab — France and Spain, expiring in 2030
- etelcalcetide — France and Italy, expiring in 2031
- blinatumomab — France, Italy and Spain, expiring in 2029
- erenumab — France, Italy and Spain, expiring in 2033
- talimogene laherparepvec — Spain, expiring in 2026; France, Germany, Italy and the United Kingdom, expiring in 2027
- apremilast — Italy, expiring in 2028

(2) A patent with this subject matter may be entitled to patent term extension in the United States.

Competition

We operate in a highly competitive environment. A number of our marketed products are indicated in disease areas in which other products or treatments are currently available or are being pursued by our competitors through research and development (R&D) activities. Additionally, some competitor-marketed products target the same genetic pathways as our recently launched marketed products or are being pursued currently. This competition could impact the pricing and market share of our products. We continue to pursue ways to increase the value of our medicines through innovations during their life cycles, which can include expanding the disease areas for which our products are indicated and finding new methods to make the delivery of our medicines easier and less costly. Such activities can offer important opportunities for differentiation. For example, we market the Neulasta® Onpro® kit, which provides physicians the opportunity to initiate the administration of the recommended dose of Neulasta® on the same day as chemotherapy, with drug delivery at home the day after chemotherapy, thereby saving patients a trip back to the doctor. We also market the AutoTouch® reusable auto-injector to be used with Enbrel Mini® single-dose prefilled cartridges (50 mg/mL). The Enbrel Mini® utilizes a drug formulation of ENBREL that was associated with statistically significant lower-mean-injection site pain than the current formulation. We plan to continue pursuing innovation efforts to strengthen our competitive position. Such position may be based on, among other things, safety, efficacy, reliability, availability, patient convenience, delivery devices, price, reimbursement, access to and timing of market entry and patent position and expiration.

Certain of the existing patents on our principal products have expired, and we face new and increasing competition, including from biosimilars and generics. A biosimilar is another version of a biological product for which marketing approval is sought or has been obtained based on a demonstration that it is “highly similar” to the original reference product. We expect that the adverse impact on our originator product sales from biosimilar competition will reflect current trends and actual results given similar conditions. We also believe that when multiple biosimilar versions of one of our originator products get approved and launched, competition could intensify more rapidly, leading to net price declines for both reference and biosimilar products, resulting in a greater impact on our products’ sales. We have seen biosimilar markets evolve differently across our major markets. For example, biosimilar adoption rates tend to be faster in the European Union (EU) than in the United States. In the United States, companies now have launched biosimilar versions of EPOGEN®, NEUPOGEN® and Neulasta® and have approved biosimilars for ENBREL. See also Government Regulation—Regulation in the United States—Approval of Biosimilars. Although we expect competitor biosimilars to compete on price, we believe many patients, providers and payers will continue to place high value on the reputation, reliability and safety of our products. As additional

biosimilar competitors come to market, we will leverage our global experience versus both branded and biosimilar competition.

We also have our own biosimilar products in the United States and outside the U.S. markets that are competing against branded and biosimilar versions of our competitors' products. In 2019, Amgen, in collaboration with Allergan, launched in the United States MVASI™, a biosimilar to Avastin® (bevacizumab), and KANJINTI™, a biosimilar to Herceptin® (trastuzumab). We have also received FDA approval for AMJEVITA™ (adalimumab-atto), a biosimilar to Humira® (adalimumab), and

AVSOLA™(infliximab-axxq), a biosimilar to Remicade® (infliximab). We expect additional biosimilar competition to both our branded and biosimilar products in the future across all markets.

In addition, although most of our products are biologics, some of our products are small molecule products. Because the FDA approval process allows generic manufacturers to rely on the safety and efficacy data of the innovator product rather than having to conduct their own costly and time-consuming clinical trials, generic manufacturers can often develop and market their competing versions of our small molecule products at much lower prices. As a result, upon the expiration or loss of patent protection for a small molecule product, we can lose the majority of revenues for that product in a very short period of time.

The introduction of new products, the development of new processes or technologies by competitors or the emergence of new information about existing products may result (i) in increased competition for our marketed products, even for those protected by patents or (ii) in reductions in the prices we receive from selling our products. In addition, the development of new treatment options or standards of care may reduce the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates. (As used in this document, the term *clinical trials* may include prospective clinical trials, observational studies, registries and other studies.) See Item 1A. Risk Factors—*Our products face substantial competition* and Item 1A. Risk Factors—*We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future*.

The following table reflects our significant competitors and is not exhaustive.

Product	Territory	Competitor-marketed product	Competitors
ENBREL	U.S. & Canada	REMICADE®*	Janssen Biotech, Inc. (Janssen)(1)
	U.S. & Canada	HUMIRA®	AbbVie Inc.
	U.S. & Canada	STELARA®(2)	Janssen(1)
Neulasta®(3)	U.S.	UDENYCA™	Coherus BioSciences, Inc.
	U.S.	Fulphila®	Mylan Institutional Inc.
	U.S. & Europe	Filgrastim biosimilars	Various
Prolia®	U.S. & Europe	Alendronate, raloxifene and zoledronate generics	Various
Aranesp®	U.S.	PROCRIT®(4)	Janssen(1)
	U.S.	MIRCERA®(5)	Galenica Group (Galenica)/F. Hoffmann-La Roche Ltd. (Roche)
	U.S. & Europe	Epoetin alfa biosimilars	Various
XGEVA®	U.S. & Europe	Zoledronate generics	Various
Sensipar®(6)/ Mimpara®	U.S. & Europe	Active vitamin D analogs	Various
EPOGEN®(3)	U.S.	MIRCERA®	Galenica/Roche
	U.S.	RETACRIT™	Hospira(7)
KYPROLIS®(9)	U.S.	NINLARO®	Millennium Pharmaceuticals, Inc.(8)
	U.S. & Europe	REVLIMID®	Celgene (10)
	U.S.	POMALYST®	Celgene (10)
	U.S.	DARZALEX®	Janssen(1)
Repatha®	U.S. & Europe	PRALUENT®	Regeneron Sanofi
Otezla®	U.S. & Europe	HUMIRA®(2)	AbbVie Inc.
	U.S. & Europe	STELARA®(2)	Janssen(1)
	U.S. & Europe	Cosentyx®(2)	Novartis
	U.S. & Europe	Methotrexate generics(2)	Various

* Approved biosimilars available.

(1) A subsidiary of Johnson & Johnson (J&J).

(2) Dermatology only.

(3) Other biosimilars under regulatory review in the United States and Europe.

(4) PROCRIT® competes with Aranesp® in supportive cancer care and predialysis settings.

(5) MIRCERA® competes with Aranesp® only in the nephrology segment.

(6) Our U.S. composition-of-matter patent for Sensipar® expired in March 2018. We are engaged in litigation with a number of companies seeking to market generic versions of Sensipar® surrounding our U.S. formulation patent that expires in September 2026. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements, for further information. Several of these generic versions of Sensipar® have been approved by the FDA.

(7) A subsidiary of Pfizer Inc.

(8) A subsidiary of Takeda Pharmaceutical Company Limited.

(9) KYPROLIS® is facing increased competition from several recently approved products.

(10) A subsidiary of Bristol-Myers Squibb Company (BMS).

Reimbursement

Sales of our principal products are dependent on the availability and extent of coverage and reimbursement from third-party payers. In many markets around the world, these payers, including government health systems, private health insurers and other organizations, remain focused on reducing the cost of healthcare, and their efforts have intensified as a result of rising healthcare costs and economic challenges. Drugs remain heavily scrutinized for cost containment. As a result, payers are becoming more restrictive regarding the use of biopharmaceutical products and scrutinizing the prices of these products while requiring a higher level of clinical evidence to support the benefits such products bring to patients and the broader healthcare system. These pressures are intensified where our products are subject to competition, including from biosimilars.

In the United States, healthcare providers and other entities such as pharmacies and pharmacy benefit managers (PBMs) are reimbursed for covered services and products they deliver through both private payer and government healthcare programs such as Medicare and Medicaid. We provide negotiated rebates to healthcare providers, private payers, government payers and PBMs. In addition, we are required to (i) provide rebates or discounts on our products that are reimbursed through certain government programs, including Medicare and Medicaid, and (ii) provide discounts to qualifying healthcare providers under the federal 340B Drug Pricing Program.

Both private and government payers utilize formularies to manage access and utilization of drugs. A drug's inclusion and favorable positioning on formulary is essential to ensure patients have access to a particular drug. Even when access is available, some patients abandon their prescriptions due to economic reasons. Payers continue to institute cost reduction and containment measures that lower drug utilization and/or spending altogether and/or shift a greater portion of the costs to patients. Such measures include, but are not limited to, more limited benefit plan designs, higher patient co-pays or coinsurance obligations, limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs), stricter utilization management criteria before a patient may get access to a drug, higher-tier formulary placement that increases the level of patient out-of-pocket costs and formulary exclusion, which effectively encourages patients and providers to seek alternative treatments or pay 100% of the cost of a drug. The use of such measures by PBMs and insurers has continued to intensify and thereby limited Amgen product usage and sales. Furthermore, over the past few years, PBMs and insurers have consolidated, resulting in a smaller number of PBMs and insurers overseeing a large portion of total covered lives in the United States. As a result, PBMs and insurers have greater market power and negotiating leverage to mandate stricter utilization criteria and/or exclude drugs from their formularies in favor of competitor drugs or alternative treatments. In highly competitive treatment markets such as with ENBREL, Otezla, Repatha® and Aimovig®, PBMs are also able to exert negotiating leverage by requiring incremental rebates from manufacturers in order to gain and/or maintain their formulary position.

In addition to market actions taken by private and government payers in the United States, policy makers from both major U.S. political parties are pursuing policies to lower drug costs. Potential policies cover a wide range of areas, including allowing importation of drugs from other countries, creating an International Pricing Index, which would set the prices of certain drugs based on those available in other countries, establishing caps on price increases based on inflation metrics, increasing greater transparency on drug pricing and utilizing third party value assessments to determine drug prices. For example, in December 2019, a drug-pricing bill, H.R. 3, passed the U.S. House of Representatives, which would, among other things, enable direct price negotiations by the federal government on certain drugs (with the maximum price paid by Medicare capped based on an international price index), include a penalty for failing to reach agreement with the government and require that manufacturers offer these negotiated prices to other payers. It also would penalize manufacturers for raising prices on drugs covered by Medicare Parts B and D faster than the rate of inflation and make other changes to the structure of Medicare Part D benefit design. The path forward on drug-pricing policy reforms remains unclear from both a congressional and administrative perspective despite all of the activity in 2019. Deliberations are continuing into 2020.

In many countries outside the United States, government-sponsored healthcare systems are the primary payers for drugs and biologics. With increasing budgetary constraints and/or difficulty in understanding the value of medicines, governments and payers in many countries are applying a variety of measures to exert downward price pressure. These measures can include mandatory price controls, price referencing, therapeutic-reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage and government-mandated price cuts. In this regard, many countries have health technology assessment organizations that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies; and these organizations are expanding in established and emerging markets. Many countries also limit coverage to populations narrower than our product label or impose volume caps to limit utilization. We expect that countries will continue to take aggressive

actions to seek to reduce expenditures on drugs and biologics. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

The dynamics and developments discussed above serve to create pressure on the pricing and potential usage of our products and the industry. Given the diverse interests in play between payers, biopharmaceutical manufacturers, policy makers, healthcare providers and independent organizations, if and whether the parties involved can achieve alignment on the matters discussed above remains unclear and the outcome of any such alignment is difficult to predict. We remain focused on delivering breakthrough treatments for unmet medical needs. Amgen is committed to working with the entire healthcare community to ensure continued innovation and to facilitate patient access to needed medicines. We do this by:

- investing billions of dollars annually in R&D;
- developing more affordable therapeutic choices in the form of high-quality and reliably-supplied biosimilars;
- pricing our medicines to reflect the value they provide;
- partnering with payers to share risk and accountability for health outcomes;
- providing patient support and education programs;
- helping patients in financial need access our medicines; and
- working with policy makers, patients and other stakeholders to establish a sustainable healthcare system with access to affordable care and where patients and their healthcare professionals are the primary decision makers.

See Item 1A. Risk Factors—*Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability* and Item 1A. Risk Factors—*Guidelines and recommendations published by various organizations can reduce the use of our products.*

Manufacturing, Distribution and Raw Materials

Manufacturing

We believe we are a leader in the manufacturing of biologics and that our manufacturing capabilities represent a competitive advantage. The products we manufacture consist of both biologics and small molecule drugs. The majority of our products are biologics that are produced in living cells and that are inherently complex due to naturally-occurring molecular variations. Highly specialized knowledge and extensive process and product characterization are required to transform laboratory-scale processes into reproducible commercial manufacturing processes. Further, our expertise in manufacturing of biologics positions us well for leadership in the global biosimilars market. For additional information regarding manufacturing facilities, see Item 2. Properties.

Our internal manufacturing network has the commercial production capabilities of bulk manufacturing, formulation, fill, finish, tableting and device assembly. These activities are performed within the United States and its territories in our Puerto Rico, Rhode Island and California facilities as well as internationally in our Ireland, Netherlands and Singapore facilities. In addition, we utilize third-party contract manufacturers to supplement the capacity or capability of our commercial manufacturing network.

To support our clinical trials, we manufacture product candidates primarily at our California facilities. We also utilize third-party contract manufacturers to supplement the capacity or capability of our overall clinical manufacturing network.

See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

Distribution

We operate distribution centers in Puerto Rico, Kentucky, California and the Netherlands for worldwide distribution of the majority of our commercial and clinical products. We also use third-party distributors to supplement distribution of our products worldwide.

Other

In addition to the manufacturing and distribution activities noted above, each of our manufacturing locations also includes key manufacturing support functions, including quality control, process development, engineering, procurement, production scheduling and warehousing. Certain of those manufacturing and distribution activities are highly regulated by the FDA as well as other international regulatory agencies. See Government Regulation—Regulation in the United States—Regulation of Manufacturing Standards.

Manufacturing Initiatives

We have multiple ongoing initiatives that are designed to extend our manufacturing advantage by optimizing our manufacturing network and/or mitigating risks while continuing to ensure adequate supply of our products.

In 2017, our next-generation biomanufacturing plant in Singapore was licensed by the FDA and the European Medicines Agency (EMA) for certain commercial-scale production. In 2019, we were approved to produce an additional product at that site. A next-generation biomanufacturing plant incorporates multiple innovative technologies into a single facility and therefore can be built in half the construction time with approximately half the operating cost of a traditional plant. Next-generation biomanufacturing plants require a smaller manufacturing footprint and offer greater environmental benefits, including reduced consumption of water and energy and lower levels of carbon emissions. Within the plants, the equipment is portable and smaller, and some components are disposable, which provides greater flexibility and speed when manufacturing different medicines simultaneously. This eliminates costly and complex retrofitting inherent in standard plants and allows Amgen to respond to changing demands for its medicines with increased agility, ultimately impacting the speed at which a medicine becomes available for patients. The Singapore site also has a plant that has been approved to produce small molecule drugs for commercial manufacturing.

In July 2018, we announced the groundbreaking of our newest next-generation biomanufacturing plant, which is being constructed at our West Greenwich, Rhode Island, campus. The new plant is expected to be the first of its kind in the United States and will use our next-generation biomanufacturing capabilities. After construction has been completed and upon approval by the FDA and other global regulatory authorities, this plant will expand our capacity to manufacture certain products for U.S. and global markets.

In 2019, we also initiated projects to expand our manufacturing capabilities in Thousand Oaks, California as well as at contract manufacturers. These investments will initially support clinical manufacturing, but in the future may also be leveraged for commercial manufacturing.

See Item 1A. Risk Factors—*Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

Raw Materials and Medical Devices

Certain raw materials, medical devices (including companion diagnostics) and components necessary for the commercial and/or clinical manufacturing of our products are provided by, and are the proprietary products of, unaffiliated third-party suppliers, certain of which may be our only sources for such materials. We currently attempt to manage the risk associated with such suppliers by inventory management, relationship management and evaluation of alternative sources when feasible. We also monitor the financial condition of certain suppliers and their ability to supply our needs. See Item 1A. Risk Factors—*We rely on third-party suppliers for certain of our raw materials, medical devices and components.*

We perform various procedures to help authenticate the source of raw materials, including intermediary materials used in the manufacture of our products, which include verification of the country of origin. The procedures are incorporated into the manufacturing processes we and our third-party contract manufacturers perform.

Government Regulation

Regulation by government authorities in the United States and other countries is a significant factor in the production and marketing of our products and our ongoing R&D activities. In order to clinically test, manufacture and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. Compliance with these standards is complex, and failure to comply with any of these standards can result in significant implications. See Item 1A. Risk Factors for a discussion of factors, including global regulatory implications, that can adversely impact our development and marketing of commercial products.

Regulation in the United States

In the United States, the Public Health Service Act, the Federal Food, Drug, and Cosmetic Act (FDCA) and the regulations promulgated thereunder, as well as other federal and state statutes and regulations govern, among other things, the production, research, development, testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising, promotion and distribution of our products in addition to the reporting of certain payments and other transfers of value to healthcare professionals and teaching hospitals.

Clinical Development and Product Approval. Drug development in our industry is complex, challenging and risky, and failure rates are high. Product development cycles are typically very long—approximately 10 to 15 years from discovery to market. A potential new medicine must undergo many years of preclinical and clinical testing to establish its safety and efficacy for use in humans at appropriate dosing levels and with an acceptable risk-benefit profile.

After laboratory analysis and preclinical testing in animals, we file an Investigational New Drug Application (IND) with the FDA to begin human testing. Typically, we undertake an FDA-designated three-phase human clinical testing program.

- In phase 1, we conduct small clinical trials to investigate the safety and proper dose ranges of our product candidates in a small number of human subjects.

- In phase 2, we conduct clinical trials to investigate side-effect profiles and the efficacy of our product candidates in a large number of patients who have the disease or condition under study.

- In phase 3, we conduct clinical trials to investigate the safety and efficacy of our product candidates in a large number of patients who have the disease or condition under study.

The FDA monitors the progress of each trial conducted under an IND and may, at its discretion, reevaluate, alter, suspend or terminate the testing based on the data accumulated to that point and the FDA's risk-benefit assessment with regard to the patients enrolled in the trial. The results of preclinical and clinical trials are submitted to the FDA in the form of either a BLA for biologic products or a New Drug Application for small molecule products. We are not permitted to market or promote a new product until the FDA has approved our marketing application.

Approval of Biosimilars. The ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. The pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on the nonclinical and clinical trial data of an originator product to which the biosimilar has been demonstrated to be "highly similar" and to have no clinically meaningful differences in terms of safety, purity and potency. The relevance of demonstrating "similarity" is that in many cases, biosimilars can be brought to market without conducting the full suite of clinical trials typically required of originators, as risk-benefit has previously been established. In order to preserve incentives for future innovation, the law establishes a period of exclusivity for originators' products, which in general prohibits biosimilars from gaining FDA approval based in part on reliance on or reference to the originator's data in their application to the FDA for 12 years after initial FDA approval of the originator product. The law does not change the duration of patents granted on biologic products. The FDA has released a number of guidance documents as part of the implementation of the abbreviated approval pathway for biosimilars, some of which remain in draft form.

Regulation of Product Marketing and Promotion. The FDA regulates the marketing and promotion of drug products. Our product promotion for approved product indications must comply with the statutory standards of the FDCA and the FDA's implementing regulations and guidance. The FDA's review of marketing and promotional activities encompasses but is not limited to direct-to-consumer advertising, healthcare-provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA may also review industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. The FDA may take enforcement action against a company for promoting unapproved uses of a product or for other violations of its advertising and labeling laws and regulations. Enforcement action may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with the FDA's regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators. Additionally, as described below, such failure may lead to additional liability under U.S. healthcare fraud and abuse laws.

Regulation of Manufacturing Standards. The FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of products prior to providing approval to market products. If after receiving approval from the FDA we make a material change in manufacturing equipment, location or process, additional regulatory review may be required. We also must adhere to current Good Manufacturing Practice regulations and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA conducts regular, periodic visits to reinspect our equipment, facilities, laboratories and processes following an initial approval.

Regulation of Combination Products. Combination products are defined by the FDA to include products composed of two or more regulated components (e.g., a biologic and/or drug and a device). Biologics/drugs and devices each have their own regulatory requirements, and combination products may have additional requirements. A

number of our marketed products meet this definition and are regulated under this framework, and we expect that a number of our pipeline product candidates will be evaluated for regulatory approval under this framework as well.

Regulation outside the United States

In EU countries as well as in Switzerland, Canada, Australia and Japan, regulatory requirements and approval processes are similar in principle to those in the United States.

In the EU, there are currently two potential tracks for seeking marketing approval for a product not authorized in any EU member state: a decentralized procedure and a centralized procedure. In the *decentralized procedure*, identical applications for marketing authorization are submitted simultaneously to the national regulatory agencies. Regulatory review is led by one member state (the reference-member state), and its assessment—based on safety, quality and efficacy—is reviewed and approved (assuming there are no concerns that the product poses a serious risk to public health) by the other member states from which the applicant is seeking approval (the concerned-member states). The decentralized procedure leads to a series of single national approvals in all relevant countries. In the *centralized procedure*, which is required of all products derived from biotechnology, a company submits a single MAA to the EMA, which conducts an evaluation of the dossier, drawing upon its scientific resources across Europe. If the drug product is proven to fulfill the requirements for quality, safety and efficacy, the EMA's Committee for Medicinal Products of Human Use (CHMP) adopts a positive opinion, which is transmitted to the EC for final decision on grant of the marketing authorization. While the EC generally follows the CHMP's opinion, it is not bound to do so. Subsequent commercialization is enabled by country-by-country reimbursement approval.

In the EU, biosimilars are approved under a specialized pathway of the centralized procedure. As with the U.S. pathway, applicants seek and obtain regulatory approval for a biosimilar once the data exclusivity period for the original reference product has expired relying in part on the data submitted for the originator product together with data evidencing that the biosimilar is "highly similar" in terms of quality, safety and efficacy to the original reference product authorized in the European Economic Area.

As a result of the United Kingdom's decision to leave the EU, the EMA, in March 2019, relocated to Amsterdam. While negotiations continue regarding the terms of the United Kingdom's withdrawal from the EU, the specific impact to the supervision, regulation and supply of medicines in the United Kingdom and Europe remain unclear.

Other countries such as Russia, Turkey and those in Latin America and the Middle East have review processes and data requirements similar to those of the EU and in some cases can rely on prior marketing approval from U.S. or EU regulatory authorities. The regulatory process in these countries may include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements.

In Asia Pacific, a number of countries such as China, Japan, South Korea and Taiwan may require local clinical trial data for bridging purposes as part of the drug registration process in addition to global clinical trials, which can add to overall drug development and registration timelines. In most of the Asian markets, registration timelines depend on marketing approval in the United States or the EU. In some markets in Asia, such as China, Indonesia and Thailand, the regulatory timelines can be less predictable. The regulatory process may also include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements. Countries such as Australia and Japan have more-mature systems that would allow for submissions in more competitive time frames. Regarding biosimilars, several of these countries have pathways to register biosimilars (e.g., Australia, India, Singapore, South Korea and Taiwan), and biosimilar products are already present on the markets (e.g., Australia and South Korea).

In some countries, such as Japan and those in the EU, medical devices may be subject to regulatory regimes whereby manufacturers must establish that their medical devices conform to essential requirements set out in the law for the particular device category. For example, in the EU, with limited exceptions, medical devices placed on the market must bear the Conformité Européenne marking to indicate their conformity with legal requirements.

Postapproval Phase

After approval, we continue to monitor adverse events and product complaints reported following the use of our products through routine post-marketing surveillance and studies when applicable. We report such events to the appropriate regulatory agencies as required per local regulations for individual cases and aggregate reports. We proactively monitor (according to good pharmacovigilance practices) and ensure implementation of signal detection, assessment and the communication of adverse events that may be associated with the use of our products. We also proactively monitor product complaints through our quality systems, which includes assessing our drug delivery devices for device complaints, adverse events and malfunctions. We may also be required by regulatory agencies to conduct further clinical trials on our marketed products as a condition of their approval or to provide additional information on safety and efficacy. Health authorities, including the FDA, have authority to mandate labeling

changes to products at any point in a product's life cycle based on new safety information or as part of an evolving label change to a particular class of products.

Health authorities, including the FDA, also have the authority, before or after approval, to require companies to implement a risk management program for a product to ensure that the benefits of the drug outweigh the risks. Each risk management program is unique and varies depending on the specific factors required. In the United States, a risk management program is known as a risk evaluation and mitigation strategy (REMS), and we currently have REMSs for Prolia®, Nplate® and BLINCYTO®.

Other Regulation

We are also subject to various laws pertaining to healthcare fraud and abuse, including anti-kickback laws and false-claims laws. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for or to induce the referral of business, including the purchase or prescribing of a particular drug that is reimbursed by a state or federal program. False-claims laws prohibit knowingly and willingly presenting or causing to be presented for payment to third-party payers (including Medicare and Medicaid), any claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as by the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). Liability under the false-claims laws may also arise when a violation of certain laws or regulations related to the underlying products (e.g., violations regarding improper promotional activity or unlawful payments) contributes to the submission of a false claim.

In 2012, Amgen entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health & Human Services (HHS), which was formally closed out in August 2018. On April 25, 2019, we entered into a settlement agreement with the U.S. Department of Justice (DOJ) and the OIG of the HHS to settle certain allegations related to our support of independent charitable organizations that provide patients with financial assistance to access their medicines. Additionally, we entered into a corporate integrity agreement that requires us to maintain a corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that in the future, our practices might be further challenged under anti-kickback or similar laws.

The U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA arguably includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations. Failure by our employees, agents, contractors, vendors, licensees, partners or collaborators to comply with FCPA and other anti-corruption laws and/or regulations could result in significant civil or criminal penalties.

We are subject to various laws and regulations globally regarding privacy and data protection. These laws and regulations relate to the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environment regarding privacy and data protection is continually evolving and developing, as these issues are the subjects of increasing amounts of attention in countries globally. For example, we are subject to the EU's General Data Protection Regulation (GDPR), which became effective on May 25, 2018, and the California Consumer Privacy Act of 2018, which became effective on January 1, 2020. Other jurisdictions where we operate have enacted or proposed similar legislation and/or regulations. Failure to comply with these laws could result in significant penalties.

Our business has been and will continue to be subject to various other U.S. and foreign laws, rules and regulations.

Research and Development and Selected Product Candidates

We focus our R&D on novel human therapeutics for the treatment of serious illness. We capitalize on our strengths in human genetics, novel biology and protein engineering. We leverage our biologic expertise and take a modality-independent approach to R&D. We use cutting-edge science and technology to study subtle biological mechanisms in search of therapies that will improve the lives of those who suffer from diseases.

Our discovery research programs may therefore yield targets that lead to the development of human therapeutics delivered as large molecules, small molecules, other combination modalities or new modalities. Leveraging more than two decades of research at deCODE, a global leader in analysis of the human genome, we are

reshaping our portfolio and increasingly focusing efforts on validated targets. Human genetic validation is used whenever possible in order to enhance the likelihood of success.

We have continued to expand our genetics validation efforts as we believe it to be a strategic advantage by acquiring a DNA-encoded library drug discovery platform, which enables efficient discovery of novel small molecule drug candidates. The platform provides access to the screening of billions of molecules and efficient optimization of drug properties in the process of identifying the drug candidate. In addition, we announced a collaboration with a focus on discovering new connections between genetics and human disease and another collaboration to participate in a consortium to provide the whole-genome sequencing of approximately 500,000 participants in the United Kingdom.

Other collaborations entered into include: one to create custom-designed proteins to improve human health and another with BeiGene to advance 20 medicines from our innovative oncology pipeline in China and globally. We anticipate utilizing data from clinical trials conducted in China to advance the development of our oncology portfolio globally.

For the years ended December 31, 2019, 2018 and 2017, our R&D expenses were $4.1 billion, $3.7 billion and $3.6 billion, respectively.

We have major R&D centers in Thousand Oaks and San Francisco, California; Iceland; and the United Kingdom, as well as smaller research centers and development facilities globally. See Item 2. Properties.

Our clinical trial activities are conducted by both our internal staff and third-party contract clinical trial service providers. To increase the number of patients available for enrollment in our clinical trials, we have opened clinical sites and will continue opening clinical sites and enrolling patients in a number of geographic locations. See Government Regulation—Regulation in the United States—Clinical Development and Product Approval for a discussion of government regulation over clinical development. Also see Item 1A. Risk Factors—*We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.*

Some of our competitors are actively engaged in R&D in areas in which we have products or in which we are developing product candidates or new indications for existing products. For example, we compete with other clinical trials for eligible patients, which may limit the number of available patients who meet the criteria for certain clinical trials. The competitive marketplace for our product candidates is greatly dependent on the timing of entry into the market. Early entry may have important advantages in gaining product acceptance, thereby contributing to a product's eventual success and profitability. Accordingly, we expect that in some cases, the relative speed with which we can develop products, complete clinical testing, receive regulatory approval and supply commercial quantities of a product to the market will be important to our competitive position.

In addition to product candidates and marketed products generated from our internal R&D efforts, we acquire companies, acquire and license certain product and R&D technology rights and establish R&D arrangements with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. In pursuing these R&D arrangements and licensing or acquisition activities, we face competition from other pharmaceutical and biotechnology companies that also seek to license or acquire technologies, product candidates or marketed products from those entities performing the R&D.

The following table shows a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 11, 2020, unless otherwise indicated. Additional product candidate information can be found on our website at www.amgen.com. (The website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.) The information in this section does not include other, nonregistrational clinical trials that we may conduct for purposes other than for submission to regulatory agencies for their approval of a new product indication.

We may conduct nonregistrational clinical trials for various reasons, including to evaluate real-world outcomes or to collect additional safety information with regard to the use of our products.

Molecule	Disease/condition
Phase 3 programs	
EVENITY®	Male osteoporosis
IMLYGIC®	Metastatic melanoma
KYPROLIS®	Multiple myeloma Weekly dosing for relapsed multiple myeloma
Nplate®	Chemotherapy-induced thrombocytopenia
Omecamtiv mecarbil	Chronic heart failure
Otezla®	Behcet's disease Genital psoriasis Mild-to-moderate psoriasis
Repatha®	Cardiovascular disease
Tezepelumab	Severe asthma
ABP 798	Rheumatoid arthritis Non-Hodgkin's lymphoma
ABP 959	Paroxysmal nocturnal hemoglobinuria
Phase 2 programs	
Rozibafusp alfa (formerly AMG 570)	Systemic lupus erythematosus
Tezepelumab	Atopic dermatitis Chronic obstructive pulmonary disease
AMG 510	Solid tumors with KRAS mutations
AMG 714/PRV-015	Celiac disease
Phase 1 programs	
AMG 119	Small-cell lung cancer
AMG 160	Prostate cancer
AMG 171	Obesity
AMG 176	Hematologic malignancies
AMG 199	Metastatic gastric and gastroesophageal junction cancer
AMG 212	Prostate cancer
AMG 330	Acute myeloid leukemia
AMG 397	Hematologic malignancies
AMG 404	Solid tumors
AMG 420	Multiple myeloma
AMG 424	Multiple myeloma
AMG 427	Acute myeloid leukemia
AMG 430	Cystic fibrosis
AMG 506	Solid tumors
AMG 562	Non-Hodgkin's lymphoma
Efavaleukin alfa (formerly AMG 592)	Inflammatory diseases
AMG 594	Cardiovascular disease
AMG 596	Glioblastoma
AMG 673	Acute myeloid leukemia
AMG 701	Multiple myeloma
AMG 757	Small-cell lung cancer
AMG 890	Cardiovascular disease

Phase 3 Clinical trials investigate the safety and efficacy of product candidates in a large number of patients who have the disease or condition under study; typically performed with registrational intent.

Phase 2

	Clinical trials investigate side-effect profiles and efficacy of product candidates in a large number of patients who have the disease or condition under study.
Phase 1	Clinical trials investigate the safety and proper dose ranges of product candidates in a small number of human subjects.

Phase 3 Product Candidate Program Changes

As of February 12, 2019, we had 12 phase 3 programs, including biosimilars. As of February 12, 2020, we had 14 phase 3 programs, as regulatory approvals were received for two programs, one program terminated, one study was completed, three programs initiated phase 3 studies and three programs were acquired from Celgene. These changes are set forth in the following table.

Molecule	Disease/condition	Program change
AVSOLA™	All approved indications for the reference product REMICADE® (infliximab)	Approved by the FDA
ENBREL	Rheumatoid arthritis remission	Study was completed
EVENITY®	Postmenopausal osteoporosis	Approved by the FDA and the EC
KYPROLIS®	Relapsed multiple myeloma	Initiated phase 3 study
Nplate®	Chemotherapy-induced thrombocytopenia	Initiated phase 3 study
Otezla®	Behcet's disease	Acquired from Celgene
	Genital psoriasis	Acquired from Celgene
	Mild-to-moderate psoriasis	Acquired from Celgene
Repatha®	Cardiovascular disease	Initiated phase 3 study
AMG 520/CNP 520	Alzheimer's disease	Terminated

Phase 3 Product Candidate Patent Information

The following table describes our composition-of-matter patents that have been issued thus far for our product candidates in phase 3 development that have yet to be approved for any indication in the United States or the EU. Patents for products already approved for one or more indications in the United States or the EU but that are currently undergoing phase 3 clinical trials for additional indications are previously described. See Marketing, Distribution and Selected Marketed Products—Patents.

Molecule	Territory	General subject matter	Estimated expiration*
Omecamtiv mecarbil	U.S.	Compound	2027
	Europe	Compound	2025
Tezepelumab	U.S.	Polypeptides	2029
	Europe	Polypeptides	2028

* Patent expiration estimates are based on issued patents, which may be challenged, invalidated or circumvented by competitors. The patent expiration estimates do not include any term adjustments, extensions or supplemental protection certificates that may be obtained in the future and thereby extend these dates. Corresponding patent applications are pending in other jurisdictions. Additional patents may be filed or issued and may provide additional exclusivity for the product candidate or its use.

Phase 3 and 2 Program Descriptions

The following provides additional information about selected product candidates that have advanced into human clinical trials.

EVENITY®

EVENITY® is a humanized monoclonal antibody that inhibits the action of sclerostin. It is being evaluated as a treatment for male osteoporosis. EVENITY® is being developed in collaboration with UCB.

In April 2019, we and UCB announced that the FDA approved EVENITY® for the treatment of osteoporosis in postmenopausal women at high risk for fracture.

In December 2019, we and UCB announced that the EC granted marketing authorization for EVENITY® for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture.

IMLYGIC®

IMLYGIC® is an oncolytic immunotherapy derived from herpes simplex virus type 1.

A phase 1b/3 study to evaluate IMLYGIC® in combination with Merck & Co., Inc.'s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with mid-stage to late-stage metastatic melanoma is ongoing.

KYPROLIS®

KYPROLIS® is a small molecule proteasome inhibitor.

In September 2019, we announced that the phase 3 CANDOR study evaluating KYPROLIS® in combination with dexamethasone and DARZALEX® compared to KYPROLIS® and dexamethasone alone in patients with relapsed multiple myeloma met its primary endpoint of PFS. In addition, a phase 3 study comparing once-weekly versus twice-weekly carfilzomib with lenalidomide and dexamethasone in subjects with relapsed multiple myeloma is ongoing.

In January 2020, a sNDA was submitted to the FDA to expand the Prescribing Information to include KYPROLIS® in combination with dexamethasone and DARZALEX® for patients with relapsed or refractory multiple myeloma based on data from the phase 3 CANDOR study.

Nplate®

Nplate® is a thrombopoietin receptor agonist. It is being investigated in a phase 3 study for early chemotherapy-induced thrombocytopenia.

Omecamtiv mecarbil

Omecamtiv mecarbil is a small molecule selective cardiac myosin activator, also called a myotrope, which directly targets the contractile mechanisms of the heart. It is being investigated in phase 3 studies for the potential treatment of heart failure with reduced ejection fraction (HFrEF). Omecamtiv mecarbil is being developed under a collaboration between Amgen and Cytokinetics, with funding and strategic support from Servier.

Otezla®

Otezla® is a small molecule that inhibits phosphodiesterase 4. It is being investigated in phase 3 studies for the treatment of oral ulcers associated with Behcet's disease, severe genital psoriasis and mild-to-moderate plaque psoriasis.

Repatha®

Repatha® is a human monoclonal antibody that inhibits PCSK9. It is being investigated in the phase 3 VESALIUS-CV cardiovascular outcomes study in high-risk patients without prior heart attack or stroke.

Rozibafusp alfa

Rozibafusp alfa is a bispecific antibody peptide conjugate that targets the B lymphocyte stimulator (BAFF) and inducible costimulatory (ICOS) ligand. It is being investigated as a treatment for systemic lupus erythematosus.

Tezepelumab

Tezepelumab is a human monoclonal antibody that inhibits the action of thymic stromal lymphopoietin. It is being evaluated as a treatment for severe asthma in an ongoing phase 3 study. It is also being investigated in phase 2 studies for atopic dermatitis and chronic obstructive pulmonary disease. Tezepelumab is being developed jointly in collaboration with AstraZeneca plc (AstraZeneca).

AMG 510

AMG 510 is a KRAS G12C small molecule inhibitor. It is being investigated as a treatment for a variety of solid tumors, including NSCLC and colorectal cancer.

AMG 714/PRV-015

AMG 714/PRV-015 is a human monoclonal antibody that binds to interleukin-15. It is being investigated for the treatment of celiac disease. Amgen reacquired the AMG 714 program in 2017. AMG 714/PRV-015 is being developed jointly in collaboration with Provention Bio.

ABP 798

ABP 798, a biosimilar candidate to rituximab (Rituxan®/MabThera®), is an anti-CD20 monoclonal antibody. It is being investigated in a phase 3 study for rheumatoid arthritis and non-Hodgkin's lymphoma. The reference-product primary conditions are non-Hodgkin's lymphoma, chronic lymphocytic leukemia and rheumatoid arthritis. ABP 798 is being developed in collaboration with Allergan.

ABP 959

ABP 959, a biosimilar candidate to eculizumab (Soliris®), is a monoclonal antibody that specifically binds to the complement protein C5. It is being investigated in a phase 3 study for paroxysmal nocturnal hemoglobinuria (PNH). The reference-product primary conditions are PNH and atypical hemolytic uremic syndrome (aHUS).

Business Relationships

From time to time, we enter into business relationships, including joint ventures and collaborative arrangements, for the R&D, manufacture and/or commercialization of products and/or product candidates. In addition, we acquire product and R&D technology rights and establish R&D collaborations with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. These arrangements generally provide for nonrefundable, upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. The activities under these collaboration agreements are performed with no guarantee of either technological or commercial success, and each is unique in nature.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require counterparties to execute confidentiality agreements upon commencement of a business relationship with us. However, others could either develop independently the same or similar information or unlawfully obtain access to our information.

Novartis

We are in a collaboration with Novartis to jointly develop and commercialize Aimovig®. In the United States, Amgen and Novartis jointly develop and collaborate on the commercialization of Aimovig®. Amgen, as the principal, recognizes product sales of Aimovig® in the United States, shares U.S. commercialization costs with Novartis and pays Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig® and other specified migraine programs. Novartis pays Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories and funds a portion of global R&D expenses. In addition, Novartis will make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds are achieved with respect to Aimovig® in the United States. Amgen manufactures and supplies Aimovig® worldwide.

We are currently involved in litigation with Novartis over our collaboration agreements for the development and commercialization of Aimovig®. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Bayer HealthCare LLC

We are in a collaboration with Bayer HealthCare LLC (Bayer) to jointly develop and commercialize Nexavar® (sorafenib). In 2015, we amended the terms of our collaboration agreement with Bayer, which terminated the co-promotion agreement in the United States and transferred all U.S. operational responsibilities to Bayer, including commercial and medical affairs activities. Prior to the termination of the co-promotion agreement, we co-promoted Nexavar® with Bayer and shared equally in the profits in the United States. In lieu of this profit share, Bayer now pays us a royalty on U.S. sales of Nexavar® at a percentage rate in the high 30s. Outside the United States and Japan, Bayer manages all commercialization activities and incurs all sales and marketing expenditures and mutually agreed R&D expenses, and we reimburse Bayer for half of those expenditures. In all countries outside the United States and Japan, we receive 50% of net profits on sales of Nexavar® after deducting certain Bayer-related costs. The rights to develop and market Nexavar® in Japan are reserved to Bayer.

DaVita Inc.

In January 2017, we entered into a six-year supply agreement with DaVita Inc. (DaVita), which superseded the previously existing, seven-year supply agreement that commenced in 2012. Pursuant to the 2017 agreement, we supply EPOGEN® and Aranesp® in amounts necessary to meet specified annual percentages of DaVita's and its

affiliates' requirements for erythropoiesis-stimulating agents (ESAs) used in providing dialysis services in the United States and Puerto Rico. Such percentages vary during the term of the agreement, but in each year are at least 90%. The agreement expires in 2022. The agreement may be terminated by either party before expiration of its term in the event of certain breaches of the agreement by the other party.

Human Resources

As of December 31, 2019, Amgen had approximately 23,400 staff members. We consider our staff relations to be good.

Information about our Executive Officers

The executive officers of the Company as of February 12, 2020, are set forth below.

Mr. Robert A. Bradway, age 57, has served as a director of the Company since 2011 and Chairman of the Board of Directors since 2013. Mr. Bradway has been the Company's President since 2010 and Chief Executive Officer since 2012. From 2010 to 2012, Mr. Bradway served as the Company's President and Chief Operating Officer. Mr. Bradway joined the Company in 2006 as Vice President, Operations Strategy and served as Executive Vice President and Chief Financial Officer from 2007 to 2010. Prior to joining the Company, Mr. Bradway was a Managing Director at Morgan Stanley in London where, beginning in 2001, he had responsibility for the firm's banking department and corporate finance activities in Europe. Mr. Bradway has been a director of The Boeing Company, an aerospace company and manufacturer of commercial airplanes, defense, space and securities systems, since 2016. He has served on the board of trustees of the University of Southern California since 2014 and on the advisory board of the Leonard D. Schaeffer Center for Health Policy and Economics at that university since 2012. From 2011 to 2017, Mr. Bradway was a director of Norfolk Southern Corporation, a transportation company.

Mr. Murdo Gordon, age 53, became Executive Vice President, Global Commercial Operations, in 2018. Prior to joining the Company, Mr. Gordon was the Chief Commercial Officer at BMS from 2016 to 2018. Mr. Gordon served as Head of Worldwide Markets at BMS from 2015 to 2016. Prior to this, Mr. Gordon served in a variety of leadership roles at BMS for more than 25 years.

Mr. Jonathan P. Graham, age 59, became Executive Vice President, General Counsel and Secretary in 2019. Mr. Graham joined the Company in 2015. From 2015 to 2019, Mr. Graham was Senior Vice President, General Counsel and Secretary. Prior to joining Amgen, from 2006 to 2015, Mr. Graham was Senior Vice President and General Counsel at Danaher Corporation. From 2004 to 2006, Mr. Graham was Vice President, Litigation and Legal Policy at General Electric Company (GE). Prior to GE, Mr. Graham was a partner at Williams & Connolly LLP.

Mr. Peter H. Griffith, age 61, became Executive Vice President and Chief Financial Officer in 2020. Mr. Griffith joined the Company in 2019 as Executive Vice President, Finance. Prior to joining Amgen, Mr. Griffith was President of Sherwood Canyon Group, LLC. From 1997 to 2019, Mr. Griffith was a Partner at EY (formerly Ernst & Young) and served in a variety of senior leadership roles, with his last position being Global Vice Chair, Corporate Development. Prior to EY, Mr. Griffith was a Managing Director and head of the investment banking division of Wedbush Securities Inc.

Ms. Lori A. Johnston, age 55, became Executive Vice President, Human Resources, in 2019. From 2016 to 2019, Ms. Johnston served as the Company's Senior Vice President, Human Resources. From 2012 to 2016, Ms. Johnston was Executive Vice President and Chief Administrative Officer of Celanese Corporation (Celanese). Prior to Celanese, Ms. Johnston served in a series of progressive leadership roles at Amgen from 2001 to 2012, with her last position being Vice President, Human Resources. Prior to joining the Company, Ms. Johnston held human resources and other positions at Dell Inc.

Ms. Cynthia M. Patton, age 58, became Senior Vice President and Chief Compliance Officer in 2012. Ms. Patton joined the Company in 2005. From 2005 to 2010, Ms. Patton was Associate General Counsel. From 2010 to 2012, Ms. Patton was Vice President, Law. Prior to joining the Company, Ms. Patton served as Senior Vice President, General Counsel and Secretary of SCAN Health Plan from 1999 to 2005.

Mr. David A. Piacquad, age 63, became Senior Vice President, Business Development in 2014. Mr. Piacquad joined the Company in 2010 and served as Vice President, Strategy and Corporate Development until his appointment to the role of Vice President, Business Development in 2014. Prior to joining the Company, from 2009 to 2010, Mr. Piacquad was Principal of David A. Piacquad Consulting LLC. From 2006 to 2009, Mr. Piacquad served as Senior Vice President, Business Development and Licensing, for Schering-Plough Corporation (Schering-Plough). Prior to Schering-Plough, Mr. Piacquad served in a series of leadership roles in finance and business development at J&J, with his last position being Vice President, Ventures and Business Development.

Dr. David M. Reese, age 57, became Executive Vice President, R&D, in 2018. Dr. Reese joined the Company in 2005 and has held leadership roles in development, medical sciences and discovery research. Dr. Reese was Senior Vice President, Translational Sciences and Oncology from 2017 to 2018 and Senior Vice President, Translational

Sciences from 2015 to 2017. Prior to joining Amgen, Dr. Reese was director of Clinical Research for the Breast Cancer International Research Group from 2001 to 2003 and a cofounder, president and chief medical officer of Translational Oncology Research International, a not-for-profit academic clinical research organization, from 2003 to 2005. Dr. Reese previously served on the faculty at University of California, Los Angeles, and the University of California, San Francisco.

Mr. Esteban Santos, age 52, became Executive Vice President, Operations in 2016. Mr. Santos joined the Company in 2007 as Executive Director, Manufacturing Technologies. From 2008 to 2013, Mr. Santos held a number of vice president roles at the Company in engineering, manufacturing, site operations and drug product. From 2013 to 2016, Mr. Santos was Senior Vice President, Manufacturing. Prior to joining the Company, Mr. Santos served as Site General Manager of J&J Cordis operation in Puerto Rico. Prior to J&J, Mr. Santos held several management positions in GE's industrial and transportation businesses.

Geographic Area Financial Information

For financial information concerning the geographic areas in which we operate, see Part IV—Note 3, Revenues and Note 11, Property, plant and equipment, to the Consolidated Financial Statements.

Investor Information

Financial and other information about us is available on our website at www.amgen.com. We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with or furnish it to the U.S. Securities and Exchange Commission (SEC). In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected without charge at the SEC's website at www.sec.gov. (These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.)

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability.

Sales of our products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers continue to pursue initiatives to manage drug utilization and contain costs. These payers are increasingly focused on the effectiveness, benefits and costs of similar treatments, which could result for our products in lower reimbursement rates or narrower populations for whom payers will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payer dynamics, may limit our ability to set or adjust the price of our products based on their value, which could have a material adverse effect on our business. In the United States, a number of legislative and regulatory proposals have been introduced in an attempt to lower drug prices. These include proposals that would, for example, allow the U.S. government to negotiate directly on drug prices, limit drug prices based on prices abroad or permit importation of drugs from Canada. Proposals addressing drug pricing are likely to continue to be introduced and may be adopted and implemented in some form.

—Changing U.S. federal coverage and reimbursement policies and practices have affected and may continue to affect access to and sales of our products

A substantial portion of our U.S. business relies on reimbursement from federal government healthcare programs and commercial insurance plans regulated by federal and state governments. See Item 1. Business—Reimbursement. Our business has and will continue to be affected by legislative actions changing U.S. federal reimbursement policy. For example, beginning in 2019, legislation requiring biopharmaceutical manufacturers to provide greater discounts on products dispensed to patients in the coverage gap between the initial coverage limit of Medicare Part D and the program's catastrophic-coverage threshold has, and will continue to, reduce our net product sales relating to such patients. Further, following the change of party control of the U.S. House of Representatives in November 2018, Congressional focus on drug pricing has increased, placing our industry under greater

Congressional scrutiny. For example, in January 2019, the chair of the House Oversight and Reform Committee sent letters to twelve different biopharmaceutical manufacturers, including Amgen, seeking documents and detailed information about such companies' drug-pricing practices. A number of other Congressional committees have also held hearings and evaluated proposed legislation on drug-pricing and payment policy. For example, in July 2019, the Senate Finance Committee advanced a bill that would, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and

D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries and require higher/ additional manufacturer discounts in Medicare Part D. In December 2019, a drug-pricing bill, H.R. 3, passed the House of Representatives, which would, among other things, enable direct price negotiations by the federal government on certain drugs (with the maximum price paid by Medicare capped based on an international index), include a penalty for failing to reach agreement with the government and require that manufacturers offer these negotiated prices to other payers. Additional legislative or regulatory proposals have been introduced by members of Congress or the Administration that, if enacted and implemented, could also affect access to and sales of our products, including but not limited to proposals to overhaul provisions of the ACA, to allow importation of prescription medications from Canada or other countries and to base Medicare payment rates on an international index price. We expect continued significant focus on health care and drug-pricing legislation through 2020 leading up to the November U.S. presidential election and beyond.

Also, our business has been, and is expected to continue to be, affected by changes in U.S. federal reimbursement policy resulting from executive actions, federal regulations and federal demonstration projects. For example, the Administration's drug-pricing blueprint released in May 2018 contains an array of policy ideas intended to increase competition, improve the negotiating power of the federal government, reduce drug prices and lower patient out-of-pocket costs with the potential to significantly affect, whether individually or collectively, our industry. Such policy ideas include, but are not limited to, moving coverage and reimbursement for Medicare Part B drugs into Medicare Part D and instituting a competitive acquisition program for Part B drugs in which competing third-party vendors take on the financial risk of acquiring drugs and billing Medicare.

Since the release of the Administration's drug-pricing blueprint, the Administration and federal agencies, including the CMS, have announced a number of demonstration projects, recommendations, policies and proposals to implement various elements of the blueprint. CMS is the federal agency responsible for administering Medicare and overseeing state Medicaid programs and Health Insurance Marketplaces and has substantial power to implement policy changes or demonstration projects that can quickly and significantly affect how drugs, including our products, are covered and reimbursed. For example, in late 2018, CMS began evaluating a pilot program that would initially, among other things, include fifty percent of Medicare Part B single source drugs and set payment amounts to more closely align with international drug prices, and in June 2019, Administration officials announced that the Office of Management and Budget was in the process of reviewing a draft proposed rule to implement this model. CMS has also issued guidance to allow certain Medicare plans offered by private insurance companies to require that patients receiving Medicare Part B drugs first try a drug preferred by the plan before covering another therapy (Step Therapy) and lowered reimbursement rates for new Medicare Part B drugs. Congress is also interested in exploring solutions that may move biopharmaceutical manufacturers from back-end rebate agreements with PBMs to front-end discounts. In December 2019, the Administration released a proposed rule to allow states (or other non-federal government entities) to submit proposals to the FDA allowing for the importation of certain prescription drugs from Canada. Such a rule could subject some of our product to importation.

Separate from the drug-pricing blueprint, CMS policy changes and demonstration projects to test new care, delivery and payment models can significantly affect how drugs, including our products, are covered and reimbursed. In ESRD, CMS uses a bundled payment system. Since 2018, Sensipar® and Parsabiv®, which are used in dialysis clinics and are curently outside of the bundled payment system, have been eligible for temporary drug add-on payment adjustments (TDAPA) and will continue to be eligible in 2020. CMS is expected to release details in 2020 on the rate setting analysis that it will conduct to determine whether and how CMS would adjust ESRD Prospective Payment System base rates to account for calcimimetics after the TDAPA for calcimimetics ends, which is expected in 2021. Additionally, in July 2019, CMS released a proposed rule creating a new mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants for ESRD patients that, if finalized as proposed, could result in changes to treatment of dialysis patients, including reduction of the use of our ESAs. In November 2019, CMS announced additional voluntary payment models for nephrologists and dialysis facility partners that also seek to encourage home dialysis and preemptive transplantation through increased risk sharing beginning in 2021. CMS has also solicited suggestions regarding other potential care models. CMS initiated in 2016 the Oncology Care Model demonstration, which provides participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare costs without negatively affecting the efficacy of care. We believe the Oncology Care Model has reduced utilization of certain of our oncology products by participating physician practices and expect it to continue to do so in the future. Additionally, in November 2019, CMS announced a request for information on the Oncology Care First model, a new voluntary model that builds on the Oncology Care Model that would be slated to begin in January 2021.

In this dynamic environment, we are unable to predict which or how many of these various federal policy, legislative, regulatory, executive or administrative changes may ultimately be enacted and implemented. However, to

the extent that these or other federal government initiatives further decrease or modify the coverage or reimbursement available for our products, require that we pay increased rebates or shift other costs to us, limit or affect our decisions regarding the pricing of or otherwise reduce the use of our U.S. products, or limit our ability to offer co-pay payment assistance to commercial patients, such actions could have a material adverse effect on our business and results of operations.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products. U.S. government price reporting regulations are complex and may require a biopharmaceutical manufacturer to update certain previously submitted data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data, we also may be required to pay additional rebates and provide additional discounts.

—Changing reimbursement and pricing actions in various states may negatively affect access to and have affected and may continue to affect sales of our products

At the state level, government actions or ballot initiatives can also affect how our products are covered and reimbursed and/or create additional pressure on our pricing decisions. A number of states have adopted, and many other states are considering, drug importation programs or other new pricing actions, including proposals designed to require biopharmaceutical manufacturers publicly to report proprietary pricing information, limit price increases or to place a maximum price ceiling or cap on biopharmaceutical products. Existing and proposed state pricing laws have added complexity to the pricing of drugs and may already be affecting industry pricing decisions. For example, in late 2017, California enacted a drug-pricing transparency bill that requires biopharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. Similar laws in Oregon and Washington were passed in 2019. States are also seeking to change the way they pay for drugs for patients covered by state programs. In January 2019, California's governor issued an executive order expanding state Medicaid coverage and directing its agencies and programs to develop a plan to consolidate drug purchases and to negotiate drug prices with biopharmaceutical manufacturers. Additionally, New York, Massachusetts and Ohio have established Medicaid drug spending caps. Additionally, Colorado, Florida, Maine and Vermont, have enacted laws, and several other states have proposed laws, to facilitate the importation of drugs from Canada. Other states could adopt similar approaches or could pursue different policy changes in a continuing effort to reduce their costs. Ultimately, as with U.S. federal government actions, existing or future state government actions or ballot initiatives may also have a material adverse effect on our product sales, business and results of operations.

—U.S. commercial payer actions have affected and may continue to affect access to and sales of our products

Payers, including healthcare insurers, PBMs, integrated healthcare delivery systems (vertically-integrated organizations built from the consolidation of healthcare insurers and PBMs) and group purchasing organizations, increasingly seek ways to reduce their costs. With increasing frequency, payers are adopting benefit plan changes that shift a greater portion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient co-pay or coinsurance obligations and more significant limitations on patients' use of manufacturer commercial co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs). Payers have sought and will likely continue to seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage, particularly in treatment areas where the payer has taken the position that multiple branded products are therapeutically comparable. Payers also control costs by imposing restrictions on access to or usage of our products, such as Step Therapy or requiring that patients receive the payer's prior authorization before covering the product or that patients use a mail-order pharmacy or a limited network of payer fully-owned mail-order or specialty pharmacies; payers may also choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. For example, some payers require physicians to demonstrate or document that the patients for whom Repatha® has been prescribed meet payer utilization management criteria, and these requirements have limited, and may continue to limit, patient access to Repatha® treatment. In an effort to reduce barriers to access, we reduced the net price of Repatha® by providing greater discounts and rebates to payers, including PBMs that administer Medicare Part D prescription drug plans. However, affordability of patient out-of-pocket co-pay cost has and may continue to limit patient use. For example, a very high percentage of Medicare patients abandoned their Repatha® prescriptions rather than pay their co-pay payment. In late 2018 and early 2019, we introduced a set of new National Drug Codes to make Repatha® available at a lower list price to attempt to address affordability for patients, particularly those on Medicare and on December 31, 2019 we discontinued the higher list price option for Repatha®. Despite these net and list price reductions, some payers have restricted and may continue to restrict patient access and may change formulary coverage for Repatha®, seek further discounts or rebates or take other actions that could reduce our sales of Repatha®. These factors have limited, and may continue to limit, patient affordability and use and negatively affect Repatha® sales.

Further, significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs which places greater pressure on pricing and usage negotiations with biopharmaceutical manufacturers, significantly

increasing discounts and rebates requirements and limiting patient access and usage. For example, in the United States, in 2018, the top three PBMs oversaw greater than two-thirds of prescription claims as well as government and commercial covered lives. The consolidation among insurers, PBMs and other payers, including through integrated healthcare delivery systems and/or with specialty or mail-order pharmacies and pharmacy retailers, has increased the negotiating leverage such entities have over us and other biopharmaceutical manufacturers and has resulted in greater price discounts, rebates and service fees realized by those payers. Also in 2018, two of

the nation's largest PBMs, Express Scripts and CVS Health, completed their combinations with major insurance companies Cigna and Aetna, respectively. Additional consolidation would further increase the leverage of such entities. Ultimately, additional discounts, rebates, fees, coverage or plan changes, restrictions or exclusions imposed by these commercial payers could have a material adverse effect on our product sales, business and results of operations. Policy reforms advanced by Congress or the Administration that refine the role of PBMs in the U.S. marketplace could have downstream implications or consequences for our business and how we interact with these entities.

—Government and commercial payer actions outside the United States have affected and will continue to affect access to and sales of our products

Outside the United States, we expect countries will continue to take actions to reduce their drug expenditures. See Item 1. Business—Reimbursement. International reference pricing (IRP) has been widely used by many countries outside the United States to control costs based on an external benchmark of a product's price in other countries. IRP policies can change quickly and frequently and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. In addition, countries may refuse to reimburse or may restrict the reimbursed population for a product when their national health technology assessments do not consider a medicine to demonstrate sufficient clinical benefit beyond existing therapies or to meet certain cost effectiveness thresholds. For example, despite the EMA's approval of Repatha® for the treatment of patients with established atherosclerotic disease, the reimbursement for Repatha® in France is limited to a narrower patient population (such as those with homozygous familial hypercholesterolemia) following a national health technology assessment. While the pricing and reimbursement process in that country remains ongoing, the assessment currently limits our efforts in France to expand Repatha® access to the broader patient population covered by the approved label. Some countries decide on reimbursement between potentially competing products through national or regional tenders that often result in one product receiving most or all of the sales in that country or region. Failure to obtain coverage and reimbursement for our products, a deterioration in their existing coverage and reimbursement, or a decline in the timeliness or certainty of payment by payers to physicians and other providers has affected and may further negatively affect the ability or willingness of healthcare providers to prescribe our products for their patients and otherwise negatively affect the use of our products or the prices we realize for them. Such changes have had, and could in the future have, a material adverse effect on our product sales, business and results of operations.

We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future.

We currently face competition from biosimilars in Europe, the United States and Canada and from generics in the United States, and we expect to face increasing biosimilar and/or generics competition this year and beyond. Expiration or successful challenge of applicable patent rights or expiration of an applicable exclusivity period has accelerated such competition, and we expect to face more litigation regarding the validity and/or scope of our patents. Our products have also experienced greater competition from lower cost biosimilars or generics that come to market when branded products that compete with our products lose their own patent protection. To the extent that governments adopt more permissive regulatory approval standards and competitors are able to obtain broader or expedited marketing approval for biosimilars and generics, the rate of increased competition for our products could accelerate.

In the EU, biosimilars are evaluated for marketing authorization pursuant to a set of general and product class-specific guidelines. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU countries and some Canadian provinces have adopted or are considering the adoption of biosimilar uptake measures such as physician prescribing quotas or automatic pharmacy substitution of biosimilars for the corresponding reference products. Some EU countries impose automatic price reductions upon market entry of one or more biosimilar competitors. While the degree of competitive effects of biosimilar competition differs between EU countries and between products, in the EU the overall use of biosimilars and the rate at which product sales of innovative products are being affected by biosimilar competition is increasing.

In the United States, the Biologics Price Competition and Innovation Act of 2009 authorized the FDA to approve biosimilars via a separate, abbreviated pathway. See Item 1. Business—Government Regulation—Regulation in the United States—Approval of Biosimilars. The first biosimilar entrant into the U.S. market was Sandoz's Zarxio®, a biosimilar version of NEUPOGEN®, in 2015. Since then, the FDA has approved additional biosimilars, including biosimilar versions of ENBREL, Neulasta® and EPOGEN®, and a growing number of companies have announced that they are also developing biosimilar versions of our products. Three biosimilar versions of Neulasta® are now marketed in the United States and we expect other biosimilar versions of Neulasta® to receive approval in 2020. Impact to our Neulasta® sales has accelerated as additional competitors have launched. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. An approved biosimilar version of EPOGEN® has also launched in the United States, and we are currently involved in patent litigations with the manufacturers of the approved biosimilar versions of ENBREL. Manufacturers of biosimilars have attempted, and may in the future attempt, to compete with our products by offering lower list prices, greater discounts or rebates, or contracts that offer longer-term pricing or a broader portfolio of other products. Companies pursuing development of biosimilar versions of our products have challenged and may continue to challenge our patents well in advance of the expiration of our material patents. For information related to our biosimilars and generics patent litigation, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. See *Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.*

The U.S. pathway includes the option for biosimilar products that meet certain criteria to be approved as interchangeable with their reference products. Some companies currently developing or already marketing biosimilars may seek to obtain interchangeable status from the FDA, which could potentially allow pharmacists to substitute those biosimilars for our reference products without prior approval from the prescriber in some states. In November 2019, the FDA issued draft guidance that provides that comparative immunogenicity studies will not generally be expected for biosimilar and interchangeable insulin products. This may open the door for other product-specific guidance development and the removal of the expectation for certain studies, which may contribute to increased biosimilar competition for our innovative products.

In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law's provisions regarding which new products receive data exclusivity. In December 2019, the Administration agreed to remove from the United States-Mexico-Canada Agreement a requirement for at least 10 years of data exclusivity for biologic products. Also, the FDA is considering whether subsequent changes to a licensed biologic would be protected by the remainder of the reference product's original 12-year exclusivity period (a concept known in the generic drug context as "umbrella exclusivity"). If the FDA were to decide that umbrella exclusivity does not apply to biological reference products or were to make other changes to the exclusivity period, this could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, legislative and regulatory efforts to promote competition through policies enabling easier generic and biosimilar approval and commercialization, including efforts to lower standards for demonstrating biosimilarity or interchangeability, limit patents that may be litigated and/or patent settlements and implement preferential reimbursement policies for biosimilars.

Upon the expiration or loss of patent protection for one of our small molecule products, we can lose the majority of revenues for that product in a very short period of time. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. Additionally, if one of our small molecule products is the subject of an FDA Written Request for pediatric studies and we are unable to adequately complete these studies, we may not obtain the pediatric exclusivity award that extends existing patents for the product by an additional six months. Our U.S. composition-of-matter patent for Sensipar®, a small molecule product, expired in March 2018. We are engaged in litigation with a number of companies seeking to market generic cinacalcet products surrounding our U.S. formulation patent that expires in September 2026. Several of these generic products have been approved by the FDA, and the manufacturer of one of the approved generic products began selling its product in late 2018 before reaching a settlement agreement with us in early January 2019. Our current litigation also includes disputes with a number of other manufacturers that began selling their approved generic cinacalcet products in the United States in early 2019. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. If we do not prevail in these matters, these manufacturers and other companies may be able to launch their approved generic products into the U.S. market. In addition, even before the resolution of our ongoing litigation, a number of other companies have elected to launch their approved generic products at risk or have sought and obtained a judicial declaration that they are permitted to launch their generic products. As a result of the product already introduced and/or that could further be introduced into the U.S. market, our product sales for Sensipar® have been adversely affected and could be further materially and adversely affected.

California is the first state to have passed legislation, effective on January 1, 2020, against “pay for delay” settlements of patent infringement claims filed by manufacturers of generics or biosimilars where anything of value is given in exchange for settlement. Under this newly-passed legislation, such settlement agreements are presumptively anticompetitive. The legislation may result in prolonged litigation and fewer settlements.

While we are unable to predict the precise effects of biosimilars and generics on our products, we are currently facing and expect to face greater competition in the United States, Europe and elsewhere this year and beyond as a result of biosimilar and generic competition and downward pressure on our product prices and sales. This competition has had and could increasingly have a material adverse effect on our product sales, business and results of operations.

Our products face substantial competition.

We operate in a highly competitive environment. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We expect that our products will compete with new drugs currently in development, drugs currently approved for other indications that may later be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. Large pharmaceutical companies and generics manufacturers of pharmaceutical products are expanding into the biotechnology field, and some pharmaceutical companies and generics manufacturers have formed partnerships to pursue biosimilars. In addition, some of our competitors may have technical, competitive or other advantages over us for the development of technologies and processes or greater experience in particular therapeutic areas, and consolidation among pharmaceutical and biotechnology companies can enhance such advantages. These advantages may make it difficult for us to compete with them successfully to discover, develop and market new products and for our current products to compete with new products or new product indications they may bring to market. As a result, our products have been competing and may continue to compete against products that offer higher rebates or discounts, lower prices, equivalent or superior efficacy, better safety profiles, easier administration, earlier market availability or other competitive features. If we are unable to compete effectively, this could reduce sales, which could have a material adverse effect on our business and results of operations.

Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. Driven by cost pressures, efforts to limit or weaken patent protection for our industry are increasing. Third parties have challenged and may continue to challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. Challenges to patents may come from potential competitors or from parties other than those who seek to market a potentially-infringing product. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We have been in the past, are currently and expect to be in the future, involved in patent litigation. These matters have included, and may in the future include, litigation with manufacturers of products that purport to be biosimilars of certain of our products for patent infringement and for failure to comply with certain provisions of the Biologics Price Competition and Innovation Act. A determination made by a court, agency or tribunal concerning infringement, validity, enforceability, injunctive or economic remedy, or the right to patent protection, for example, are typically subject to appellate or administrative review. Upon review, such initial determinations may be afforded little or no deference by the reviewing tribunal and may be affirmed, reversed or made the subject of reconsideration through further proceedings. A patent dispute or litigation has not discouraged, and may not in the future discourage, a potential violator from bringing the allegedly-infringing product to market prior to a final resolution of the dispute or litigation. The period from inception until resolution of a patent dispute or litigation is subject to the availability and schedule of the court, agency or tribunal before which the dispute or litigation is pending. We have been, and may in the future be, subject to competition during this period and may not be able to recover fully from the losses, damages and harms we incur from infringement by the competitor product even if we prevail. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities, be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Further, under the Hatch-Waxman Act, our products approved by the FDA under the FDCA have been, and may in the future be, the subject of patent litigation with generics competitors before expiry of the five-year period of data exclusivity provided for under the Hatch-Waxman Act and prior to the expiration of the patents listed for the product. Likewise, our innovative biologic products have been, and may in the future be, the subject of patent litigation prior

to the expiration of our patents and, with respect to competitors seeking approval as a biosimilar or interchangeable version of our products, prior to the 12-year exclusivity period provided under the ACA. In addition, we are facing patent litigation involving claims that the biosimilar product candidates we are working to develop infringe the patents of other companies, including those that manufacture, market or sell the applicable reference products or who are developing or have developed other biosimilar versions of such products. For example, we are currently engaged in litigation in the United States regarding MVASI™ and KANJINTI™. While we have attempted, and may

continue to attempt, to challenge the patents held by other companies, our efforts may be unsuccessful. Alternatively, such patents have contributed, and may in the future contribute, to a decision by us to not pursue all of the same labeled indications as are held by these companies. For information related to our patent litigation, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Certain of the existing patents on our products have expired. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents. As our patents expire, competitors are able to legally produce and market similar products or technologies, including biosimilars, which has had, and may continue to have, a material adverse effect on our product sales, business and results of operations. In addition, competitors have been, and may continue to be, able to invalidate, design around or otherwise circumvent our patents and sell competing products.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. Professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities. Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies. In addition, a growing number of organizations are providing assessments of the value and pricing of biopharmaceutical products, and even organizations whose guidelines have historically been focused on clinical matters have begun to incorporate analyses of the cost effectiveness of various treatments into their treatment guidelines and recommendations. Value assessments may come from private organizations that publish their findings and offer recommendations relating to the products' reimbursement by government and private payers. Some companies and payers have announced pricing and payment decisions based in part on the assessments of private organizations. For example, CVS Caremark indicated in August 2018 that it will begin utilizing third-party cost effectiveness analyses to make formulary and coverage determinations for newly-approved drugs. In addition, government health technology assessment organizations in many countries make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service effects of new, emerging and existing medicines and treatments. Such health technology assessment organizations have recommended, and may in the future recommend, reimbursement for certain of our products for a narrower indication than was approved by applicable regulatory agencies or may recommend against reimbursement entirely. Such recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could have a material adverse effect on our product sales, business and results of operations. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price of our common stock.

Our current products and products in development cannot be sold without regulatory approval.

Our business is subject to extensive regulation by numerous state and federal government authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in foreign countries to obtain approval from regulatory authorities before we manufacture, market and sell our products. Once our products are approved, the FDA and other U.S. and foreign regulatory agencies have substantial authority to require additional testing and reporting, perform inspections, change product labeling or mandate withdrawals of our products. Failure to comply with applicable regulatory requirements may subject us to administrative and/or judicially imposed sanctions or monetary penalties as well as reputational and other harms. The sanctions could include the FDA's or foreign regulatory authorities' refusals to approve pending applications, delays in obtaining or withdrawals of approvals, delays or suspensions of clinical trials, warning letters, product recalls or seizures, total or partial suspensions of our operations, injunctions, fines, civil penalties and/or criminal prosecutions.

Obtaining and maintaining regulatory approvals have been, and will continue to be, increasingly difficult, time-consuming and costly. Legislative bodies or regulatory agencies could enact new laws or regulations, change existing laws or regulations, or change their interpretations of laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products or product candidates. The rate and degree of change in existing laws and regulations and regulatory expectations have accelerated in established markets, and regulatory expectations continue to evolve in emerging markets. We are unable to predict whether and when any further changes to laws or regulatory policies affecting our business could occur, such as changes to laws or regulations governing manufacturer communications concerning drug products and drug product candidates and whether such changes could have a material adverse effect on our product sales, business and results of operations. In the United States, a partial federal government shutdown halted the work of many federal agencies and their employees from late December 2018 through late January 2019. A subsequent extended shutdown could result in reductions or delays of FDA's activities,

including with respect to our ongoing clinical programs, our manufacturing of our products and product candidates and our product approvals.

Regulatory authorities have questioned, and may in the future question, the sufficiency for approval of the endpoints we select for our clinical trials. A number of our products and product candidates have been evaluated in clinical trials using surrogate endpoints that measure an effect that is known to correlate with an ultimate clinical benefit. For example, a therapeutic oncology product candidate may be evaluated for its ability to reduce or eliminate minimal residual disease (MRD), or to extend the length of time during and after the treatment that a patient lives without the disease worsening, measured by PFS. Demonstrating that the product candidate induces MRD-negative responses or produces a statistically significant improvement in PFS does not necessarily mean that the product candidate will show a statistically significant improvement in overall survival or the time that the patients remain alive. In the cardiovascular setting, a heart disease therapeutic candidate may be evaluated for its ability to reduce low-density lipoprotein cholesterol (LDL-C) levels, as an elevated LDL-C level has been a surrogate endpoint for cardiovascular events such as death, heart attack and stroke. The use of surrogate endpoints such as PFS and LDL-C reduction, in the absence of other measures of clinical benefit, may not be sufficient for broad usage or approval even when such results are statistically significant. Regulatory authorities could also add new requirements, such as the completion of enrollment in a confirmatory study or the completion of an outcomes study or a meaningful portion of an outcomes study, as conditions for obtaining approval or obtaining an indication. For example, despite demonstrating that Repatha® reduced LDL-C levels in a broad patient population, only after our large phase 3 outcomes study evaluating the ability of Repatha® to prevent cardiovascular events met certain of its primary composite endpoint and key secondary composite endpoint did the FDA grant a broader approval of Repatha® to reduce the risk of certain cardiovascular events, and also to be used, alone or in combination with other lipid-lowering therapies, for the treatment of adults with primary hyperlipidemia to reduce LDL-C. There may also be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to other existing treatment options can be shown. The imposition of additional requirements or our inability to meet them in a timely fashion or at all has delayed, and may in the future delay, our clinical development and regulatory filing efforts, delay or prevent us from obtaining regulatory approval for new product candidates or new indications for existing products, or prevent us from maintaining our current labels.

Some of our products have been approved by U.S. and foreign regulatory authorities on an accelerated or conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, in March 2018, we announced that the FDA approved BLINCYTO® under accelerated approval for the treatment of adults and children with B-cell precursor acute lymphoblastic leukemia in first or second complete remission with MRD greater than or equal to 0.1 percent. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Regulatory authorities are placing greater focus on monitoring products originally approved on an accelerated or conditional basis and on whether the sponsors of such products have met the conditions of the accelerated or conditional approvals. If we are unable to fulfill the regulators' requirements that were conditions of a product's accelerated or conditional approval and/or if regulators re-evaluate the data or risk-benefit profile of our product, the conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change the product's labeled indications or even withdraw the product from the market.

Regulatory authorities can also impose post-marketing pediatric study requirements. Failure to fulfill such requirements may result in regulatory or enforcement action, including financial penalties or the invalidation of a product's marketing authorization.

Safety problems or signals can arise as our products and product candidates are evaluated in clinical trials, including investigator sponsored studies, or as our marketed products are used in clinical practice. We are required continuously to collect and assess adverse events reported to us and to communicate to regulatory agencies these adverse events and safety signals regarding our products. Regulatory agencies periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. In the United States, for our products with approved REMS (see Item 1. Business—Government Regulation—Postapproval Phase), we are required to submit periodic assessment reports to the FDA to demonstrate that the goals of the REMS are being met. REMS and other risk management programs are designed to ensure that a drug's benefits outweigh the risks and vary in the elements they contain. If the FDA is not satisfied with the results of the periodic assessment reports we submit for any of our REMS, the FDA may also modify our REMS or take other regulatory actions, such as implementing revised or restrictive labeling. The drug delivery devices approved for use in combination with our products are also subject to regulatory oversight and review for safety and malfunctions. If regulatory agencies determine that we or other parties (including our clinical trial investigators, those operating our patient support programs or licensees of our products) have not complied with the applicable reporting, other pharmacovigilance or other safety or quality assessment requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including fines, marketing authorization withdrawal and other penalties. Our product candidates and marketed

products can also be affected by safety problems or signals occurring with respect to products that are similar to ours or that implicate an entire class of products. Further, as a result of clinical trials, including sub-analyses or meta-analyses of earlier clinical trials (a meta-analysis involves the use of various statistical methods to combine results from previous separate but related studies) performed by us or others, concerns may arise about the sufficiency of the data or studies underlying a product's approved label. Such actual or perceived safety problems or concerns can lead to:

- revised or restrictive labeling for our products, or the potential for restrictive labeling that has resulted, and may in the future result, in our decision not to commercialize a product candidate;

- requirement of risk management or minimization activities or other regulatory agency compliance actions related to the promotion and sale of our products;

- post-marketing commitments, mandated post-marketing requirements or pharmacovigilance programs for our approved products;

- product recalls of our approved products;

- required changes to the processes used in the manufacture of our products, which could increase our manufacturing costs and affect the availability of contract manufacturers we may utilize to assist in such manufacturing;

- revocation of approval for our products from the market completely, or within particular therapeutic areas or patient types;

- increased timelines or delays in being approved by the FDA or other regulatory bodies; and/or

- treatments or product candidates not being approved by regulatory bodies.

For example, after an imbalance in positively adjudicated cardiovascular serious adverse events was observed in one of the phase 3 clinical trials for EVENITY® but not in another, larger phase 3 study, in April 2019 the FDA approved EVENITY® for the treatment of osteoporosis in postmenopausal women at high risk for fracture, along with a post-marketing requirement. The requirement includes a five-year observational feasibility study that could be followed by a comparative safety study or trial.

In addition to our innovative products, we are working to develop and commercialize biosimilar versions of a number of products currently manufactured, marketed and sold by other pharmaceutical companies. In some markets, there is not yet a legislative or regulatory pathway for the approval of biosimilars. In the United States, the ACA provided for such a pathway; while the FDA continues to implement it, discussions continue as to the evidence needed to demonstrate biosimilarity or interchangeability for specific products. See *We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future.* Delays or uncertainties in the development or implementation of such pathways could result in delays or difficulties in getting our biosimilar products approved by regulatory authorities, subject us to unanticipated development costs or otherwise reduce the value of the investments we have made in the biosimilars area. Further, we cannot predict whether any repeal or reform of the ACA or other legislation or policy initiatives would affect the biosimilar pathway or have a material adverse effect on our development of biosimilars or on our marketed biosimilars. In addition, if we are unable to bring our biosimilar products to market on a timely basis and secure "first-to-market" or other advantageous positions, our future biosimilar sales, business and results of operations could be materially and adversely affected.

We may not be able to develop commercial products despite significant investments in R&D.

Amgen invests heavily in R&D. Successful product development in the biotechnology industry is highly uncertain, and very few R&D projects produce commercial products. Product candidates, including biosimilar product candidates, or new indications for existing products (collectively, product candidates) that appear promising in the early phases of development may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results, for reasons that could include changes in the standard of care of medicine;

- the product candidate was not effective or not more effective than currently available therapies in treating a specified condition or illness;

- the product candidate was not cost effective in light of existing therapeutics;
- the product candidate had harmful side effects in animals or humans;
- the necessary regulatory bodies, such as the FDA or EMA, did not approve the product candidate for an intended use;
- the product candidate was not economical for us to manufacture and commercialize;
- other parties had or may have had proprietary rights relating to our product candidate, such as patent rights, and did not let us sell it on reasonable terms, or at all;
- we and certain of our licensees, partners, contracted organizations or independent investigators may have failed to effectively conduct clinical development or clinical manufacturing activities;

- the pathway to regulatory approval or reimbursement for product candidates was uncertain or not well-defined;

- the biosimilar product candidate failed to demonstrate the requisite biosimilarity to the applicable reference product, or was otherwise determined by a regulatory authority to not meet applicable standards for approval; and

- a companion diagnostic device that is required with the use of a product candidate is not approved by the necessary regulatory authority.

We have spent considerable time, energy and resources developing our expertise in human genetics and acquiring access to libraries of genetic information with the belief that genetics could meaningfully aid our search for new medicines and help guide our R&D decisions and investments. We have focused our R&D strategy on drug targets validated by genetic or other compelling human evidence. However, product candidates based on genetically validated targets remain subject to the uncertainties of the drug development process and may not reach the market for a number of reasons, including the factors listed above.

A number of our product candidates have failed or been discontinued at various stages in the product development process. For example, in May 2015, we terminated our participation in the co-development and commercialization of brodalumab, a product candidate in phase 3, with AstraZeneca. The decision was based on events of suicidal ideation and behavior in the brodalumab program that occurred late in the development program, which we believed likely would necessitate restrictive labeling that would limit the appropriate patient population. Inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product for any of the reasons discussed could potentially have a negative effect on our product sales and earnings and could result in a significant impairment of in-process research and development (IPR&D) or other intangible assets.

We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.

Before we sell any products, we must conduct clinical trials to demonstrate that our product candidates are safe and effective for use in humans. The results of those clinical trials are used as the basis to obtain approval from regulatory authorities such as the FDA and EMA. See *Our current products and products in development cannot be sold without regulatory approval*. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims. The length of time, number of trial sites and number of patients required for clinical trials vary substantially, and we may spend several years and incur substantial expense in completing certain clinical trials. In addition, we may have difficulty finding a sufficient number of clinical trial sites and patients to participate in our clinical trials, particularly if competitors are conducting clinical trials in similar patient populations. Patients may withdraw from clinical trials at any time, and privacy laws and/or other restrictions in certain countries may restrict the ability of clinical trial investigators to conduct further follow-up on such patients, which may adversely affect the interpretation of study results. Delays and complications in planned clinical trials can result in increased development costs, associated delays in regulatory approvals and in product candidates reaching the market and revisions to existing product labels.

Further, to increase the number of patients available for enrollment in our clinical trials, we have opened, and will continue to open, clinical sites and enroll patients in a number of locations where our experience conducting clinical trials is more limited, including Russia, India, China, South Korea, the Philippines, Singapore and some Central and South American countries, either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to understand the unique regulatory environments of individual countries. Further, we must ensure the timely production, distribution and delivery of the clinical supply of our product candidates to numerous and varied clinical trial sites. Additionally, regional disruptions, including natural disasters or health emergencies (such as novel viruses or pandemics), could significantly disrupt the timing of clinical trials. If we fail to adequately manage the design, execution and diverse regulatory aspects of our large and complex clinical trials or to manage the production or distribution of our clinical supply, or such sites experience disruptions as a result of a natural disaster or health emergency, corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates or could lose our ability to market existing products in certain therapeutic areas or altogether. If we are unable to market and sell our products or product candidates or to obtain approvals in

the timeframe needed to execute our product strategies, our business and results of operations could be materially and adversely affected.

We rely on independent third-party clinical investigators to recruit patients and conduct clinical trials on our behalf in accordance with applicable study protocols, laws and regulations. Further, we rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations. In some circumstances, we enter into co-development arrangements with other pharmaceutical and medical devices companies that provide for the other company to conduct certain clinical trials for the product we are co-developing or to develop a diagnostic test used in screening or monitoring patients in our clinical trials. See *Some of our pharmaceutical pipeline and of our commercial product sales relies on collaborations with third parties, which may adversely affect the development and sale of our products.* We also may acquire companies that have past or ongoing clinical trials or rights

to products or product candidates for which clinical trials have been or are being conducted. These trials may not have been conducted to the same standards as ours; however, once an acquisition has been completed we assume responsibility for the conduct of these trials, including any potential risks and liabilities associated with the past and prospective conduct of those trials. If regulatory authorities determine that we or others, including our licensees or co-development partners, or the independent investigators or vendors selected by us, our co-development partners or by a company we have acquired or from which we have acquired rights to a product or product candidate, have not complied with regulations applicable to the clinical trials, those authorities may refuse or reject some or all of the clinical trial data or take other actions that could delay or otherwise negatively affect our ability to obtain or maintain marketing approval of the product or indication. In addition, delays or failures to develop diagnostic tests for our clinical trials can affect the timely enrollment of such trials and lead to delays or inability to obtain marketing approval. If we were unable to market and sell our products or product candidates, our business and results of operations could be materially and adversely affected.

In addition, some of our clinical trials utilize drugs manufactured and marketed by other pharmaceutical companies. These drugs may be administered in clinical trials in combination with one of our products or product candidates or in a head-to-head study comparing the products' or product candidates' relative efficacy and safety. In the event that any of these vendors or pharmaceutical companies have unforeseen issues that negatively affect the quality of their work product or create a shortage of supply, or if we are otherwise unable to obtain an adequate supply of these other drugs, our ability to complete our applicable clinical trials and/or evaluate clinical results may also be negatively affected. As a result, such quality or supply problems could adversely affect our ability to timely file for, gain or maintain regulatory approvals worldwide.

Clinical trials must generally be designed based on the current standard of medical care. However, in certain diseases, such as cancer, the standard of care is evolving rapidly. In some cases, we may design a clinical trial based on the standard of care we anticipate will exist at the time our study is completed. The duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on standards of medical care that are no longer or that have not become the current standards by the time such trials are completed, limiting the utility and application of such trials. Additionally, the views of regulatory agencies relating to the requirements for accelerated approval may change over time, and trial designs that were sufficient to support accelerated approvals for some oncology products may not be considered sufficient for later candidates. We may not obtain favorable clinical trial results and therefore may not be able to obtain regulatory approval for new product candidates or new indications for existing products and/or maintain our current product labels. Participants in clinical trials of our products and product candidates may also suffer adverse medical events or side effects that could, among other factors, delay or terminate clinical trial programs and/or require additional or longer trials to gain approval.

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a risk management plan for our product or for approval of a new indication. For example, in connection with the June 2011 ESA label changes, we agreed to and conducted additional clinical trials examining the use of ESAs in CKD. Additional clinical trials we initiate, including those required by the FDA, could result in substantial additional expense and the outcomes could result in further label restrictions or the loss of regulatory approval for an approved indication, each of which could have a material adverse effect on our product sales, business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our products, our business and results of operations.

Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.

Many of our products and product candidates may be used in combination with a drug delivery device, such as an injector or other delivery system. For example, Neulasta® is available as part of the Neulasta® Onpro® kit, and our AutoTouch® reusable autoinjector is used with Enbrel Mini® single-dose prefilled cartridges. In addition, some of our products or product candidates, including many of our oncology products in early stage development, may also require the use of a companion or other diagnostic device such as a device that determines whether the patient is eligible to use our drug or that helps ensure its safe and effective use. In some regions, including the United States, regulatory authorities may require contemporaneous approval of the companion diagnostic device and the therapeutic product; in others the regulatory authorities may require a separate study of the companion diagnostic device. Our product candidates or expanded indications of our products used with such devices may not be approved or may be substantially delayed in receiving regulatory approval if development or approval of such devices is delayed, such devices do not also gain or maintain regulatory approval or clearance, or if such devices do not remain commercially available. When approval of the product and device is sought under a single marketing drug application, the increased complexity of the review process may delay receipt of regulatory approval. In addition, some of these

devices may be provided by single-source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies to supply and/or market the devices and, in some cases, to conduct the studies required for approval or clearance by the applicable regulatory agencies. We are also dependent on those third-party companies continuing to meet applicable regulatory or other requirements. Failure to successfully develop, modify, or supply the devices, delays in or failures of the Amgen or third-party studies, or failure of us or the third-party companies to obtain or maintain regulatory approval or clearance of the devices could

result in increased development costs; delays in, or failure to obtain or maintain, regulatory approval; and/or associated delays in a product candidate reaching the market or in the addition of new indications for existing products. We are also required to collect and assess user complaints, adverse events and malfunctions regarding our devices, and actual or perceived safety problems or concerns with a device used with our product can lead to regulatory actions and adverse effects on our products. See *Our current products and products in development cannot be sold without regulatory approval.* Additionally, regulatory agencies conduct routine monitoring and conduct inspections to identify and evaluate potential issues with our devices. For example, in 2017, the FDA reported on its adverse event reporting system that it is evaluating our Neulasta® Onpro® kit. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop, supply, or gain or maintain approval for these devices could adversely affect sales of the related, approved products.

Some of our pharmaceutical pipeline and our commercial product sales relies on collaborations with third parties, which may adversely affect the development and sale of our products.

We depend on alliances with other companies, including pharmaceutical and biotechnology companies, vendors and service providers, for the development of a portion of the products in our pharmaceutical pipeline and for the commercialization and sales of certain of our commercial products. For example, we have collaborations with third parties under which we share development rights, obligations and costs and/or commercial rights and obligations. See Item 1. Business—Significant Developments—Collaboration with BeiGene, Ltd., and Item 1. Business—Business Relationships.

Failures by these parties to meet their contractual, regulatory, or other obligations to us or any disruption in the relationships between us and these third parties, could have a material adverse effect on our pharmaceutical pipeline and business. In addition, our collaborative relationships for R&D and/or commercialization and sales often extend for many years and have given, and may in the future give, rise to disputes regarding the relative rights, obligations and revenues of us and our collaboration partners, including the ownership or prosecution of intellectual property and associated rights and obligations. This could result in the loss of intellectual property rights or protection, delay the development and sale of potential pharmaceutical products, affect the effective sale and delivery of our commercialized products and lead to lengthy and expensive litigation, administrative proceedings or arbitration. For example, we are currently involved in litigation with Novartis over our collaboration agreements for the development and commercialization of Aimovig®. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. While our collaboration remains in place until the litigation is resolved and we remain committed to continuing to work with Novartis to sell and deliver Aimovig®, it is possible that the dispute may nevertheless affect the efficiency of operation and future growth of the collaboration. The litigation may also affect or delay, or lead to a termination of, other projects with Novartis.

The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability.

We are subject to income and other taxes in the United States and other jurisdictions in which we do business. As a result, our provision for income taxes is derived from a combination of applicable tax rates in the various places we operate. Significant judgment is required for determining our provision for income tax.

Our tax returns are routinely examined by tax authorities in the United States and other jurisdictions in which we do business, and a number of audits are currently underway. Tax authorities, including the Internal Revenue Service (IRS), are becoming more aggressive in their audits and are particularly focused on the allocations of income and expense among tax jurisdictions. As previously disclosed, we received a Revenue Agent Report (RAR) from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Although final resolution of this complex matter is not likely within the next 12 months, such resolution could have a material negative effect on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments substantially greater or less than amounts accrued.

Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities and changes in applicable tax laws, regulations or administrative interpretations thereof. The Tax Cuts and Jobs Act (the 2017 Tax Act) is complex and further regulations and interpretations are still being issued. We could face audit challenges to our application of the new law that could have a negative effect on our provision for income taxes. A change to the U.S. tax system, such as a repeal or modification of the 2017 Tax Act, a change to the tax system in a jurisdiction where we have

significant operations, such as the U.S. territory of Puerto Rico, or changes in tax law in the United States or other jurisdictions where we do business, could have a material and adverse effect on our business and on the results of our operations.

We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.

The global supply of our products and product candidates for commercial sales and for use in our clinical trials is significantly dependent on the uninterrupted and efficient operation of our manufacturing facilities, in particular those in the U.S. territory of Puerto Rico and Thousand Oaks, California. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales*.

We currently perform a substantial majority of our clinical manufacturing that supports our product candidates at our facility in Thousand Oaks, California. A substantial disruption in our ability to operate our Thousand Oaks manufacturing facility could materially and adversely affect our ability to supply our product candidates for use in our clinical trials, leading to delays in development of our product candidates.

In addition, we currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico. In recent years, Puerto Rico has been affected by natural disasters, including earthquakes in early 2020 and Hurricane Maria in 2017. These natural disasters have affected public and private properties and Puerto Rico's electric grid and communications networks. While the critical manufacturing areas of our commercial manufacturing facility were not significantly affected by these natural disasters, the restoration of electrical service on the island after Hurricane Maria was a slow process, and our facility operated with electrical power from backup diesel powered generators for some time. We are also operating on backup generators since the early 2020 earthquakes. Further instability of the electric grid could require us to increase the use of our generators or to continue using them exclusively. In addition, future storms or other natural disasters or events could cause a more significant effect on our manufacturing operations. Also, during the summer of 2019 political instability in the Puerto Rico government led to civil unrest and the resignation and replacement of the governor. Although our ability to manufacture and supply our products has not, to date, been affected by these natural disasters or the political instability, any substantial disruption to our ability to operate our Puerto Rico manufacturing facility or get supplies and manufactured products transported to and from that location could materially and adversely affect our ability to supply our products and affect our product sales. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales*.

Hurricane Maria, the earthquakes of early 2020 and the political situation in Puerto Rico have placed greater stress on the island's already challenged economy. Beginning in 2016, the government of Puerto Rico defaulted on its roughly $72 billion in debt. In response, the U.S. Congress passed the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA), which established a Financial Oversight and Management Board (Oversight Board) to provide fiscal oversight. Title III of PROMESA provides Puerto Rico with a judicial process for restructuring its debt similar to, but not identical to, Chapter 9 of the U.S. Bankruptcy Code, including a stay of debtholder litigation. In May 2017, the Oversight Board approved and certified the filing in the U.S. District Court for the District of Puerto Rico of a voluntary petition under Title III of PROMESA for the government of Puerto Rico and certain of its governmental entities, including the Puerto Rico Electric Power Authority. Certain creditors and labor unions have brought suit claiming the appointment process of the Oversight Board was unconstitutional, and as of October 2019, the U.S. Supreme Court heard oral arguments on these claims. If the U.S. Supreme Court were to hold that PROMESA has a constitutional infirmity and that actions taken by the Oversight Board are invalid, the commencement of all Title III proceedings could be invalid and the current debt restructuring process and the debtholder litigation stay under Title III of PROMESA could be in jeopardy.

Each year since 2017, the Oversight Board has prepared and updated Puerto Rico's fiscal plan and has certified its budget, imposing significant expense reductions across the government, considering federal disaster funding related to Hurricane Maria and projecting material deficits once the stimulus effects of the disaster recovery dissipate. Each plan has stressed the need for fiscal and structural reforms to address Puerto Rico's challenging economic and demographic trends. The government of Puerto Rico challenged several budget measures imposed by the Oversight Board; these challenges have been dismissed by the Title III Court and affirmed by the U.S. Court of Appeals for the First Circuit.

In addition, the 2017 Tax Act no longer permits deferral of U.S. taxation on Puerto Rico earnings, although these earnings generally will be taxed in the United States at a reduced 10.5% rate. Given Puerto Rico's challenged

economy and disaster recovery needs, it may be difficult for Puerto Rico to sustain or grow its manufacturing base, which contributes significantly to Puerto Rico's economy, due to competition from other locations subject to similar levels of taxation.

While PROMESA and the actions above continue to be important factors in moving Puerto Rico toward economic stability, Puerto Rico's ongoing economic and demographic trend challenges and political situation, the effects of natural disasters and the

effects of the 2017 Tax Act or other potential tax law changes have negatively affected, and may in the future negatively affect, the territorial government's provision of utilities or other services in Puerto Rico that we use in the operation of our business and could create the potential for increased taxes or fees to operate in Puerto Rico, result in a migration of workers from Puerto Rico to the mainland United States, or make it more expensive or difficult for us to operate in Puerto Rico. These factors could have a material adverse effect on our ability to supply our products, on our business and on our product sales.

We rely on third-party suppliers for certain of our raw materials, medical devices and components.

We rely on unaffiliated third-party suppliers for certain raw materials, medical devices and components necessary for the manufacturing of our commercial and clinical products. Certain of those raw materials, medical devices and components are proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug applications with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until the regulatory agency approved such supplier. For example, Scandinavian Health Limited Group is our single source of SureClick® autoinjectors for Repatha®, ENBREL, Aimovig®, AMGEVITA™ and Aranesp®. Also, certain of the raw materials required in the commercial and clinical manufacturing of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues, bovine serum and human serum albumin.

Among the reasons we may be unable to obtain these raw materials, medical devices and components include:

- regulatory requirements or action by regulatory agencies or others;
- adverse financial or other strategic developments at or affecting the supplier, including bankruptcy;
- unexpected demand for or shortage of raw materials, medical devices or components;
- failure to comply with our quality standards which results in quality and product failures, product contamination and/or recall;
- a material shortage, contamination, recall and/or restrictions on the use of certain biologically derived substances or other raw materials;
- discovery of previously unknown or undetected imperfections in raw materials, medical devices or components;
- cyber-attacks on supplier systems; and
- labor disputes or shortages, including from the effects of health emergencies (such as novel viruses or pandemics) and natural disasters.

For example, in prior years we have experienced shortages in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility. Further quality issues that result in unexpected additional demand for certain components may lead to shortages of required raw materials or components (such as we have experienced with EPOGEN® glass vials). We may experience similar or other shortages in the future resulting in delayed shipments, supply constraints, clinical trial delays, contract disputes and/or stock-outs of our products. These or other similar events could negatively affect our ability to satisfy demand for our products or conduct clinical trials, which could have a material adverse effect on our product sales, business and results of operations.

Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

Manufacturing biologic and small molecule human therapeutic products is difficult, complex and highly regulated. We manufacture many of our commercial products and product candidates internally. In addition, we currently use third-party contract manufacturers to produce, or assist in the production of, a number of our products, and we currently use contract manufacturers to produce, or assist in the production of, a number of our late-stage product candidates and drug delivery devices. See Item 1. Business—Manufacturing, Distribution and Raw Materials—Manufacturing. Our ability to adequately and timely manufacture and supply our products (and product candidates

to support our clinical trials) is dependent on the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers, which may be affected by:

- capacity of manufacturing facilities;
- contamination by microorganisms or viruses, or foreign particles from the manufacturing process;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of health emergencies (such as novel viruses or pandemics) or natural disasters;

- compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs and production success rates and yields;
- updates of manufacturing specifications;
- contractual disputes with our suppliers and contract manufacturers;
- timing and outcome of product quality testing;
- power failures and/or other utility failures;
- cyber-attacks on supplier systems;
- breakdown, failure, substandard performance or improper installation or operation of equipment (including our information technology systems and network-connected control systems or those of our contract manufacturers or third-party service providers); and/or
- delays in the ability of the FDA or foreign regulatory agencies to provide us necessary reviews, inspections and approvals, including as a result of a subsequent extended U.S. federal government shutdown.

If any of these or other problems affect production in one or more of our facilities or those of our third-party contract manufacturers, or if we do not accurately forecast demand for our products or the amount of our product candidates required in clinical trials, we may be unable to start or increase production in our unaffected facilities to meet demand. If the efficient manufacture and supply of our products or product candidates is interrupted, we may experience delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends, contract disputes and/or recalls of our products. From time to time we have initiated recalls of certain lots of our products. For example, in July 2014 we initiated a voluntary recall of an Aranesp® lot distributed in the EU after particles were detected in a quality control sample following distribution of that lot, and in April 2018 we initiated a precautionary recall of two batches of Vectibix® distributed in Switzerland after potential crimping defects were discovered in the metal seals on some product vials. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could have a material adverse effect on our product sales, business and results of operations.

Our manufacturing processes, those of our third-party contract manufacturers and those of certain of our third-party service providers must undergo regulatory approval processes and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build, validate and license another manufacturing plant and it can take longer than three years to qualify and license a new contract manufacturer or service provider. If we elect or are required to make changes to our manufacturing processes because of new regulatory requirements, new interpretations of existing requirements or other reasons, this could increase our manufacturing costs and result in delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends or contract negotiations or disputes. Such manufacturing challenges may also occur if our existing contract manufacturers are unable or unwilling to timely implement such changes, or at all.

In addition, regulatory agencies conduct routine monitoring and conduct inspections of our manufacturing facilities and processes as well as those of our third-party contract manufacturers and service providers. If regulatory authorities determine that we or our third-party contract manufacturers or certain of our third-party service providers have violated regulations, they may mandate corrective actions and/or issue warning letters, or even restrict, suspend or revoke our prior approvals, prohibiting us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. See also *Our current products and products in development cannot be sold without regulatory approval.* Such issues may also delay the approval of product candidates we have submitted for regulatory review, even if such product candidates are not directly related to the products, devices or processes at issue with regulators. Because our third-party contract manufacturers and certain of our third-party service providers are subject

to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis or at all. See *A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems and network-connected control systems and our data, interrupt the operation of our business and affect our reputation.* If we or our third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers fail to supply materials, products or services to us, we may experience delayed shipments, delays in our clinical trials, supply constraints, contract disputes, stock-outs and/or recalls of our products. Additionally, we distribute a substantial volume of our commercial products through our primary distribution centers in Louisville, Kentucky for the United States and in Breda, Netherlands for Europe and much of the rest of the world. We also conduct most of the labeling and packaging of our products distributed in Europe and much of the rest of the world in Breda. Our ability to timely supply products is dependent on

the uninterrupted and efficient operations of our distribution and logistics centers, our third-party logistics providers and our labeling and packaging facility in Breda. Further, we rely on commercial transportation, including air and sea freight, for the distribution of our products to our customers, which may be negatively affected by natural disasters or security threats.

Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively affect our business.

Certain of our distributors, customers and payers have substantial purchasing leverage, due to the volume of our products they purchase or the number of patient lives for which they provide coverage. The substantial majority of our U.S. product sales is made to three pharmaceutical product wholesaler distributors: AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc. These distributors, in turn, sell our products to their customers, which include physicians or their clinics, dialysis centers, hospitals and pharmacies. One of our products, EPOGEN®, is sold primarily to free-standing dialysis clinics. DaVita owns or manages a large number of the outpatient dialysis facilities located in the United States and accounts for approximately 80% of all EPOGEN® sales. Similarly, as discussed above, there has been significant consolidation in the health insurance industry, including that a small number of PBMs now oversee a substantial percentage of total covered lives in the United States. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability*. The three largest PBMs in the United States are now part of major health insurance providers. The growing concentration of purchasing and negotiating power by these entities may put pressure on our pricing due to their ability to extract price discounts on our products, fees for other services or rebates, negatively affecting our bargaining position, sales and/or profit margins. In addition, decisions by these entities to purchase or cover less or none of our products in favor of competitive products could have a material adverse effect on our product sales, business and results of operations due to their purchasing volume. Further, if one of our significant wholesale distributors encounters financial or other difficulties and becomes unable or unwilling to pay us all amounts that such distributor owes us on a timely basis or at all, it could negatively affect our business and results of operations. In addition, if one of our significant wholesale distributors becomes insolvent or otherwise unable to continue its commercial relationship with us in its present form, it could significantly disrupt our business and adversely affect our product sales, our business and results of operations unless suitable alternatives are timely found or lost sales are absorbed by another distributor.

Our efforts to collaborate with or acquire other companies, products, or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.

We seek innovation through significant investment in both internal R&D and external transactions including collaborations, partnering, alliances, licenses, joint ventures, mergers and acquisitions (collectively, acquisition activity). Acquisition activities may be subject to regulatory approvals or other requirements that are not within our control. There can be no assurance that such regulatory or other approvals will be obtained or that all closing conditions required in connection with our acquisition activities will be satisfied or waived, which could result in us being unable to complete the planned acquisition activities.

Acquisition activities are complex, time consuming and expensive and may result in unanticipated costs, delays or other operational or financial problems related to integrating the acquired company and business with our company, which may divert our management's attention from other business issues and opportunities and restrict the full realization of the anticipated benefits of such transactions within the expected timeframe or at all. We may pay substantial amounts of cash, incur debt or issue equity securities to pay for acquisition activities, which could adversely affect our liquidity or result in dilution to our stockholders, respectively. Further, failures or difficulties in integrating or retaining new personnel or in integrating the operations of the businesses, products or assets we acquire (including related technology, commercial operations, compliance programs, manufacturing, distribution and general business operations and procedures) may affect our ability to realize the benefits of the transaction and grow our business and may result in us incurring asset impairment or restructuring charges. These and other challenges may arise in connection with our recent acquisition of Otezla® and/or collaboration with BeiGene, or with other acquisition activities, which could have a material adverse effect on our business, results of operations and stock price.

Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.

As we continue our expansion efforts in emerging markets around the world, through acquisitions and licensing transactions as well as through the development and introduction of our products in new markets, we face numerous

risks to our business. There is no guarantee that our efforts and strategies to expand sales in emerging markets will succeed. Emerging market countries, including China, may be especially vulnerable to periods of global and local political, legal, regulatory and financial instability, including sovereign debt issues and/or the imposition of international sanctions in response to certain state actions. We may also be required to increase our reliance on third-party agents and unfamiliar operations and arrangements previously utilized by companies we partner with or acquire in emerging markets. See *We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications*. As we expand internationally, we are subject to fluctuations in foreign currency exchange rates relative to the U.S. dollar. While we have a program in place that is designed to

reduce our exposure to foreign currency exchange rate fluctuations through foreign currency hedging arrangements, our hedging efforts do not completely offset the effect of these fluctuations on our revenues and earnings. In addition, we have a number of financial instruments referencing the London Interbank Offered Rate (LIBOR). On July 27, 2017, the U.K Financial Conduct Authority, which regulates LIBOR, announced that it will no longer require banks to submit rates for the calculation of LIBOR to the LIBOR administrator after 2021, and it is anticipated that LIBOR will be phased out and replaced by 2022. While various replacement reference rates have been proposed, an alternative reference rate to LIBOR has not yet been widely adopted and the specific mechanisms to replace LIBOR in our existing LIBOR-linked financial instruments have not been finalized. As such, the replacement of LIBOR could have an adverse effect on the market for, or value of, our LIBOR-linked financial instruments.

Our international operations and business may also be subject to less protective intellectual property or other applicable laws, diverse data privacy and protection requirements, changing tax laws and tariffs, trade restrictions or other barriers designed to protect industry in the home country against foreign competition, far-reaching anti-bribery and anti-corruption laws and regulations and/or evolving legal and regulatory environments. Our expansion efforts in emerging markets around the world, including China, is dependent upon the establishment of an environment that is supportive of biopharmaceutical innovation, sustained access for our products and limited pricing controls. We are also subject to the economic and political uncertainties stemming from the United Kingdom's exit from the EU, commonly referred to as "Brexit," which occurred on January 31, 2020. While our manufacturing and packaging activities take place largely outside the United Kingdom, minimizing the need to make costly and significant changes to those operations, we have nevertheless been working to put in place contingency plans to attempt to mitigate the effects of Brexit on us. Overall, the legal and operational challenges of our international business operations, along with government controls, the challenges of attracting and retaining qualified personnel and obtaining and/or maintaining necessary regulatory or pricing approvals of our products, may result in a material adverse effect on our international product sales, business and results of operations.

Our business may be affected by litigation and government investigations.

We and certain of our subsidiaries are involved in legal proceedings. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. Civil and criminal litigation is inherently unpredictable, and the outcome can result in costly verdicts, fines and penalties, exclusion from federal healthcare programs and/or injunctive relief that affect how we operate our business. Defense of litigation claims can be expensive, time consuming and distracting, and it is possible that we could incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our product sales, business and results of operations. In addition, product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention and could adversely affect our reputation and the demand for our products. We and certain of our subsidiaries have previously been named as defendants in product liability actions for certain of our products.

We are also involved in government investigations that arise in the ordinary course of our business. In recent years, there has been a trend of increasing government investigations and litigations against companies operating in our industry, both in the United States and around the world. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability.* Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. We cannot ensure that all our employees, agents, contractors, vendors, licensees, partners or collaborators will comply with all applicable laws and regulations. On April 25, 2019, we entered into a settlement agreement with the DOJ and the OIG of the HHS to settle certain allegations relating to our support of independent charitable organizations that provide patients with financial assistance to access their medicines. As a result, we entered into a corporate integrity agreement that requires us to maintain a corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years. While we expect to fully comply with all of our obligations under the corporate integrity agreement, failure to do so could result in substantial penalties and our being excluded from government healthcare programs. We may also see new government investigations of or actions against us citing novel theories of recovery. For example, prosecutors are placing greater scrutiny on commercial co-pay support programs, and further enforcement actions and investigations regarding such programs could limit our ability to provide co-pay assistance to commercial patients. Any of these results could have a material adverse effect on our business and results of operations.

A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems and network-connected control systems and our data, interrupt the operation of our business and affect our reputation.

To achieve our business objectives, we rely to a large extent upon sophisticated information technology systems, including cloud services and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or affect our reputation.

Our information technology systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. The complexity and interconnected nature of our systems makes them potentially vulnerable to breakdown or other service interruptions. Our systems are also subject to frequent cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity and are becoming increasingly difficult to detect. Such attacks could include the use of harmful and virulent malware, including ransomware or other denials of service, and can be deployed through various means including the software supply chain, e-mail, malicious websites and the use of social engineering. Attacks such as those seen with other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access important data needed to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and/or distributing our products. For example, in 2017, a pharmaceutical company experienced a cyberattack involving virulent malware that significantly disrupted its operations, including its research and sales operations and the production of some of its medicines and vaccines. As a result of the cyberattack, its orders and sales for certain products in certain markets were negatively affected. Our systems also contain and utilize a high volume of sensitive data, including intellectual property, trade secrets, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials and/or personal information belonging to us, our staff, our patients, customers and/or other parties. In some cases, we utilize third-party service providers to process, store, manage or transmit such data, which may increase our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) or lapses by employees, service providers (including providers of information technology-specific services), nation states, organized crime organizations, "hacktivists" or others, create risks that our sensitive data may be exposed to unauthorized persons, our competitors, or the public. Finally, domestic and global government regulators, our business partners, suppliers with whom we do business, companies that provide us or our partners with business services and companies we may acquire may face similar risks, and security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. For example, in 2019, two vendors that perform testing and analytical services that we use in developing and manufacturing our products have experienced cyberattacks requiring us to disconnect our systems from the vendors' systems. While we were able to reconnect our systems following restoration of the vendor's capabilities without significantly affecting product availability, a more extended service outage affecting this or other vendors, particularly where such vendor is the single source from which we obtain the services, could have a material adverse effect on our business or results of operations. In addition, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers.

Although we have experienced system breakdowns, attacks and information security breaches, we do not believe such breakdowns, attacks and breaches have had a material adverse effect on our business or results of operations. We continue to invest in the monitoring, protection and resilience of our critical or sensitive data and systems. However, there can be no assurance that our efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks, or breaches of our systems that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in financial, legal, business or reputational harm to us or negatively affect our stock price. While we maintain cyber-liability insurance, our insurance is not sufficient to cover us against all losses that could potentially result from a service interruption, breach of our systems or loss of our critical or sensitive data.

We are also subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and developing and the subject of significant attention globally. For example, we are subject to the EU's GDPR, which became effective in May 2018, and the California Consumer Privacy Act of 2018, which became effective in January 2020, each of which contemplate substantial penalties (penalties for noncompliance could be 4% of an organization's annual global revenues under the GDPR. Other jurisdictions where we operate have enacted or proposed similar

legislation and/or regulations. Failure to comply with these current and future laws could result in significant penalties and could have a material adverse effect on our business and results of operations.

Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Our operations and performance have been, and may continue to be, affected by global economic conditions. Financial pressures may cause government or other third-party payers to more aggressively seek cost containment measures. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability*. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships may also affect patients' ability to afford health care as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to reduced demand for our products, which could have a material adverse effect on our product sales, business and results of operations. Economic conditions may also adversely affect the ability of our distributors, customers and suppliers to obtain the liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Although we monitor our distributors', customers' and suppliers' financial condition and their liquidity to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could have a material adverse effect on our product sales, business and results of operations. A significant worsening of global economic conditions could materially increase these risks facing us.

We maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our consolidated balance sheets. The value of our investments may be adversely affected by interest rate fluctuations, downgrades in credit ratings, illiquidity in the capital markets and other factors that may result in other-than-temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on sales of investments.

Our stock price is volatile.

Our stock price, like that of our peers in the biotechnology and pharmaceutical industries, is volatile. Our revenues and operating results may fluctuate from period to period for a number of reasons. Events such as a delay in product development, changes to our expectations or strategy or even a relatively small revenue shortfall may cause financial results for a period to be below our expectations or projections. As a result, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Announcements or discussions, including via social media channels, of possible restrictive actions by government or private payers that would negatively affect our business or industry if ultimately enacted or adopted may also cause our stock price to fluctuate, whether or not such restrictive actions ever actually occur. Similarly, actual or perceived safety issues with our products or similar products or unexpected clinical trial results can have an immediate and rapid effect on our stock price, whether or not our operating results are materially affected.

We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The capital and credit markets may experience extreme volatility and disruption, which may lead to uncertainty and liquidity issues for both borrowers and investors. We expect to access the capital markets to supplement our existing funds and cash generated from operations in satisfying our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we strategically plan to pursue, including acquisitions and licensing activities. In the event of adverse capital and credit market conditions, we may be unable to obtain capital market financing on similar favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Changes in credit ratings issued by nationally recognized credit-rating agencies could adversely affect our ability to obtain capital market financing and the cost of such financing and have an adverse effect on the market price of our securities.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

As of December 31, 2019, we owned or leased approximately 190 properties. The locations and primary functions of significant properties are summarized in the following tables:

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Excluded from the information above are (i) undeveloped land and leased properties that have been abandoned and (ii) certain buildings that we still own but are no longer used in our business. There are no material encumbrances on our owned properties.

We believe that our facilities are suitable for their intended uses and, in conjunction with our third-party contracting manufacturing agreements, provide adequate capacity and are sufficient to meet our expected needs. See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

See Item 1. Business—Manufacturing, Distribution and Raw Materials.

Item 3. LEGAL PROCEEDINGS

Certain of the legal proceedings in which we are involved are discussed in Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements, and are hereby incorporated by reference.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Common stock

Our common stock trades on the NASDAQ Global Select Market under the symbol AMGN. As of February 6, 2020, there were approximately 5,493 holders of record of our common stock.

Performance graph

The following graph shows the value of an investment of $100 on December 31, 2014, in each of Amgen common stock, the Amex Biotech Index, the Amex Pharmaceutical Index and Standard & Poor's 500 Index (S&P 500). All values assume reinvestment of the pretax value of dividends and are calculated as of December 31 of each year. The historical stock price performance of the Company's common stock shown in the performance graph is not necessarily indicative of future stock price performance.

performancegraphit52019.jpg

	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019
Amgen (AMGN)	$100.00	$103.97	$96.12	$117.57	$135.31	$172.68
Amex Biotech (BTK)	$100.00	$111.39	$90.06	$124.11	$124.44	$149.87
Amex Pharmaceutical (DRG)	$100.00	$104.18	$95.49	$111.37	$119.66	$141.66
S&P 500 (SPX)	$100.00	$101.37	$113.49	$138.33	$132.29	$173.93

The material in this performance graph is not soliciting material, is not deemed filed with the SEC and is not incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made on, before or after the date of this filing and irrespective of any general incorporation language in such filing.

Stock repurchase program

During the three months and year ended December 31, 2019, we had one outstanding stock repurchase program, under which the repurchasing activity was as follows:

	Total number of shares purchased	Average price paid per share[1]	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program[2]
October 1 - October 31	2,500,729	$ 199.94	2,500,729	$ 3,064,464,667
November 1 - November 30	1,349,900	$ 222.55	1,349,900	$ 2,764,044,387
December 1 - December 31	1,218,800	$ 237.95	1,218,800	$ 6,474,033,251
	5,069,429	$ 215.10	5,069,429	
January 1 - December 31	40,244,414	$ 189.85	40,244,414	

(1) Average price paid per share includes related expenses.

(2) In May 2019 and December 2019, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $5.0 billion and $4.0 billion, respectively.

Dividends

For the years ended December 31, 2019 and 2018, we paid quarterly dividends. We expect to continue to pay quarterly dividends, although the amount and timing of any future dividends are subject to approval by our Board of Directors. Additional information required by this item is incorporated herein by reference to Part IV—Note 16, Stockholders' equity, to the Consolidated Financial Statements.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

Information about securities authorized for issuance under existing equity compensation plans is incorporated by reference from Item 12—Securities Authorized for Issuance Under Existing Equity Compensation Plans.

Item 6. SELECTED FINANCIAL DATA

Consolidated Statements of Income Data:	Years ended December 31, 2019	2018	2017	2016	2015
	(In millions, except per-share data)				
Revenues:					
Product sales	$ 22,204	$ 22,533	$ 21,795	$ 21,892	$ 20,944
Other revenues	1,158	1,214	1,054	1,099	718
Total revenues	$ 23,362	$ 23,747	$ 22,849	$ 22,991	$ 21,662
Operating expenses:					
Cost of sales	$ 4,356	$ 4,101	$ 4,069	$ 4,162	$ 4,227
Research and development	$ 4,116	$ 3,737	$ 3,562	$ 3,840	$ 4,070
Selling, general and administrative	$ 5,150	$ 5,332	$ 4,870	$ 5,062	$ 4,846
Net income[1]	$ 7,842	$ 8,394	$ 1,979	$ 7,722	$ 6,939
Diluted earnings per share[1]	$ 12.88	$ 12.62	$ 2.69	$ 10.24	$ 9.06
Dividends paid per share	$ 5.80	$ 5.28	$ 4.60	$ 4.00	$ 3.16

Consolidated Balance Sheets Data:	As of December 31, 2019	2018	2017	2016	2015
	(In millions)				
Total assets	$ 59,707	$ 66,416	$ 79,954	$ 77,626	$ 71,449
Total debt[2]	$ 29,903	$ 33,929	$ 35,342	$ 34,596	$ 31,429
Total stockholders' equity[3]	$ 9,673	$ 12,500	$ 25,241	$ 29,875	$ 28,083

In addition to the following notes, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, Part IV—Consolidated Financial Statements and accompanying notes and previously filed Annual Reports on Form 10-K for further information regarding our consolidated results of operations and financial position for periods reported therein and for known factors that will affect the comparability of future results. Also see Part IV—Note 16, Stockholders' equity, to the Consolidated Financial Statements, for information regarding cash dividends declared per share of common stock for each of the four quarters of 2019, 2018 and 2017. In addition, our Board of Directors declared dividends per share of $1.00 and $0.79 that were paid in each of the four quarters of 2016 and 2015, respectively.

(1) In 2017, we recorded a net charge of $6.1 billion as a result of the 2017 Tax Act. See Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

(2) See Part IV—Note 15, Financing arrangements, to the Consolidated Financial Statements, for discussion of our financing arrangements. In 2016, we issued $7.3 billion of debt and repaid $3.7 billion of debt. In 2015, we issued $3.5 billion of debt and repaid $2.4 billion of debt.

(3) Throughout the five years ended December 31, 2019, we had a stock repurchase program authorized by the Board of Directors, through which we repurchased $7.6 billion, $17.9 billion, $3.1 billion, $3.0 billion and $1.9 billion, respectively, of Amgen common stock.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis (MD&A) is intended to assist the reader in understanding Amgen's business. MD&A is provided as a supplement to, and should be read in conjunction with, our consolidated financial statements and accompanying notes. Our results of operations discussed in MD&A are presented in conformity with U.S. generally accepted accounting principles (GAAP). Amgen operates in one business segment: human therapeutics. Therefore, our results of operations are discussed on a consolidated basis.

Forward-looking statements

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. In addition, we, or others on our behalf, may make forward-looking statements in press releases, written statements or our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Such words as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume" and "continue" as well as variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and they involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in Part I, Item 1A. Risk Factors. We have based our forward-looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecasted by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, earnings per share (EPS), liquidity and capital resources, trends, planned dividends, stock repurchases and restructuring plans. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

Amgen is a biotechnology company committed to unlocking the potential of biology for patients suffering from serious illnesses. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential. In 2020, we celebrate our 40th anniversary, continuing our history of focusing on innovative medicines that have the potential to be first-in-class molecules and that have a large-effect size on serious diseases.

Our principal products—those with the most significant annual commercial sales—are ENBREL, Neulasta®, Prolia®, XGEVA®, Aranesp®, KYPROLIS®, EPOGEN® and our recently acquired product Otezla®. We also market a number of other products, including Nplate®, Vectibix®, Repatha®, Parsabiv®, Sensipar®/Mimpara®, BLINCYTO®, Aimovig®, NEUPOGEN®, KANJINTI™, AMGEVITA™, EVENITY®, MVASI™, IMLYGIC® and Corlanor®. For additional information about our products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products.

Our strategy includes integrated activities intended to maintain and strengthen our competitive position in the industry. We focus on six commercial areas: inflammation, oncology/hematology, bone health, cardiovascular disease, nephrology and neuroscience and conduct discovery research primarily in three therapeutic areas: inflammation, oncology/hematology and cardiovascular/metabolic diseases. In 2019, we advanced our innovative pipeline, launched branded biosimilar programs, built our global geographic reach and expanded our next generation manufacturing capabilities, while returning capital to shareholders.

During the year we delivered strong financial results while facing competition from biosimilars and generics. Total product sales decreased 1% as lower net selling prices were offset partially by volume growth. Product sales decreased 5% in the United States and grew 11% in the rest of the world. Total operating expenses increased 2% as we invested in our innovative R&D pipeline, including our early oncology assets.

We continued to advance our pipeline, including AMG 510, which was granted fast track designation from the FDA for the treatment of patients with previously treated metastatic NSCLC with KRAS G12C mutation. We launched EVENITY® in the United States and Japan, and it was granted marketing authorization in Europe; and the United States label for KYPROLIS® was expanded. We also continued to advance our biosimilar program with the launches of KANJINTI™ and MVASI™ in the United States and the approval of AVSOLA™ for all approved indications of the reference product REMICADE® (infliximab) in the United States. Lastly, we made a regulatory submission for ABP 798 in the United States.

We have also continued to invest in external opportunities to augment our internal programs and products. We completed our acquisition of worldwide rights to Otezla®, the only oral, non-biologic treatment for psoriasis and psoriatic arthritis. We strengthened our international footprint with the announcement of a strategic collaboration with BeiGene to expand our oncology presence in China. In addition, we expanded our human genetics capabilities, by entering into a collaboration with a regional healthcare system in the United States and joining a consortium to perform whole genome sequencing of approximately 500,000 participants from the United Kingdom. Our human genetics capabilities allow us to identify new development targets in our chosen areas of therapeutic focus.

Cash flows from operating activities were $9.2 billion, enabling us to invest in our business while returning capital to shareholders through the payment of cash dividends and stock repurchases. For 2019, we increased our quarterly cash dividend by 10% to $1.45 per share of common stock. In December 2019, we declared a cash dividend of $1.60 per share of common stock for the first quarter of 2020, an increase of 10% for this period, to be paid in March 2020. We also repurchased 40.2 million shares of our common stock throughout 2019 at an aggregate cost of $7.6 billion.

Our long-term success depends, to a great extent, on our ability to continue to discover, develop and commercialize innovative products and acquire or collaborate on therapies currently in development by other companies. We must develop new products to achieve revenue growth and to offset revenue losses when products lose their exclusivity or when competing products are launched. Certain of our products face increasing pressure from competition, including biosimilars and generics. For additional information, including information on the expirations of patents for various products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents, and Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We devote considerable resources to R&D activities, but successful product development in the biotechnology industry is highly uncertain and we also are facing increasing regulatory scrutiny of safety and efficacy both before and after products launch.

Rising healthcare costs and economic conditions also continue to pose challenges to our business, including continued pressure by third-party payers, such as governments and private payers, to reduce healthcare expenditures. As a result of public and private healthcare-provider focus, the industry continues to experience significant pricing pressures and other cost containment measures. Finally, wholesale and end-user buying patterns can affect our product sales. These effects can cause fluctuations in quarterly product sales and have generally not been significant when comparing full-year product performance to the prior year.

See Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products and Part I, Item 1A. Risk Factors for further discussion of certain of the factors that could impact our future product sales.

Selected Financial Information

The following is an overview of our results of operations (in millions, except percentages and per-share data):

	Year ended December 31, 2019	Change	Year ended December 31, 2018
Product sales:			
U.S.	$ 16,531	(5)%	$ 17,429
Rest of world (ROW)	5,673	11 %	5,104
Total product sales	22,204	(1)%	22,533
Other revenues	1,158	(5)%	1,214
Total revenues	$ 23,362	(2)%	$ 23,747
Operating expenses	$ 13,688	2 %	$ 13,484
Operating income	$ 9,674	(6)%	$ 10,263
Net income	$ 7,842	(7)%	$ 8,394
Diluted EPS	$ 12.88	2 %	$ 12.62
Diluted shares	609	(8)%	665

In the following discussion of changes in product sales, any reference to unit demand growth or decline refers to changes in the purchases of our products by healthcare providers such as physicians or their clinics, dialysis centers, hospitals and pharmacies. In addition, any reference to increases or decreases in inventory refers to changes in inventory held at wholesaler customers and end users such as pharmacies.

Total product sales decreased for 2019, driven primarily by a decline in net selling price, offset partially by higher unit demand. For 2020, we expect net selling price to continue to decline.

Other revenues decreased for 2019, driven primarily by lower milestone payments, offset partially by higher royalties.

Operating expenses increased for 2019, driven primarily by higher spending in research and early pipeline in support of our oncology programs, offset partially by an impairment charge associated with an IPR&D asset in 2018.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is offset partially by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material in 2019, 2018 or 2017.

Results of Operations

Product sales

Worldwide product sales were as follows (dollar amounts in millions):

	Year ended December 31, 2019	Change	Year ended December 31, 2018	Change	Year ended December 31, 2017
ENBREL	$ 5,226	4 %	$ 5,014	(8 %	$ 5,433
Neulasta®	3,221	(28 %	4,475	(1 %	4,534
Prolia®	2,672	17 %	2,291	16 %	1,968
XGEVA®	1,935	8 %	1,786	13 %	1,575
Aranesp®	1,729	(8 %	1,877	(9 %	2,053
KYPROLIS®	1,044	8 %	968	16 %	835
EPOGEN®	867	(14 %	1,010	(8 %	1,096
Sensipar®/Mimpara®	551	(69 %	1,774	3 %	1,718
Other products	4,959	49 %	3,338	29 %	2,583
Total product sales	$ 22,204	(1 %	$ 22,533	3 %	$ 21,795
Total U.S.	$ 16,531	(5 %	$ 17,429	2 %	$ 17,131
Total ROW	5,673	11 %	5,104	9 %	4,664
Total product sales	$ 22,204	(1 %	$ 22,533	3 %	$ 21,795

Future sales of our products will depend in part on the factors discussed in the Overview, Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition, in Part I, Item 1A. Risk Factors, and any additional factors discussed in the individual product sections below. In addition, for a list of our products' significant competitors, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition.

ENBREL

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2019	Change	Year ended December 31, 2018	Change	Year ended December 31, 2017
ENBREL — U.S.	$ 5,050	5 %	$ 4,807	(8 %	$ 5,206
ENBREL — Canada	176	(15 %	207	(9 %	227
Total ENBREL	$ 5,226	4 %	$ 5,014	(8 %	$ 5,433

The increase in ENBREL sales for 2019 was driven primarily by favorable impacts from changes in accounting estimates of sales deductions and an increase in net selling price, offset partially by lower unit demand. For 2020, we expect the trend of lower unit demand to continue.

The decrease in ENBREL sales for 2018 was driven primarily by lower unit demand and net selling price.

In April 2019, the FDA approved a second biosimilar version of ENBREL, and we are involved in patent litigations with the two companies seeking to market their FDA-approved biosimilar versions of ENBREL. See Part

IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. Other companies are also developing proposed biosimilar versions of ENBREL. Companies with approved biosimilar versions of ENBREL may seek to enter the U.S. market if we are not successful in our litigations, or even earlier.

Neulasta®

Total Neulasta® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2019	Change	Year ended December 31, 2018	Change	Year ended December 31, 2017
Neulasta® — U.S.	$ 2,814	(27%)	$ 3,866	(2%)	$ 3,931
Neulasta® — ROW	407	(33%)	609	1%	603
Total Neulasta®	$ 3,221	(28%)	$ 4,475	(1%)	$ 4,534

The decrease in global Neulasta® sales for 2019 was driven by the impact of biosimilar competition on net selling price and unit demand. Neulasta® sales for 2019 included a $98 million order in the first quarter from the U.S. government.

The decrease in global Neulasta® sales for 2018 was driven primarily by favorable changes in accounting estimates of product returns in 2017, offset partially by favorable changes in inventory. Neulasta® sales for 2018 included a $55 million order in the fourth quarter from the U.S. government.

Biosimilar versions of Neulasta® have been approved and launched, and other biosimilar versions may also receive approval in the near future. Therefore, we face increased competition in the United States and Europe, which has had and will continue to have a material adverse impact on sales of Neulasta®. For a discussion of ongoing patent litigations related to these and other biosimilars, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Prolia®

Total Prolia® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2019	Change	Year ended December 31, 2018	Change	Year ended December 31, 2017
Prolia® — U.S.	$ 1,772	18%	$ 1,500	18%	$ 1,272
Prolia® — ROW	900	14%	791	14%	696
Total Prolia®	$ 2,672	17%	$ 2,291	16%	$ 1,968

The increases in global Prolia® sales for 2019 and 2018 were driven by higher unit demand. Prolia®, which has a six-month dosing interval, has exhibited a historical sales pattern, with the first and third quarters of a year representing lower sales than the second and fourth quarters of a year.

XGEVA®

Total XGEVA® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2019	Change	Year ended December 31, 2018	Change	Year ended December 31, 2017
XGEVA® — U.S.	$ 1,457	9%	$ 1,338	16%	$ 1,157
XGEVA® — ROW	478	7%	448	7%	418
Total XGEVA®	$ 1,935	8%	$ 1,786	13%	$ 1,575

The increases in global XGEVA® sales for 2019 and 2018 were driven primarily by higher unit demand.

Aranesp®

Total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2019	Change	Year ended December 31, 2018	Change	Year ended December 31, 2017
Aranesp® — U.S.	$ 758	(20 %)	$ 942	(15 %)	$ 1,114
Aranesp® — ROW	971	4 %	935	— %	939
Total Aranesp®	$ 1,729	(8 %)	$ 1,877	(9 %)	$ 2,053

The decreases in global Aranesp® sales for 2019 and 2018 were driven primarily by the impact of competition on unit demand in the United States.

Aranesp® faces competition from a long-acting ESA. Aranesp® also faces competition from a biosimilar version of EPOGEN®. Other biosimilar versions of EPOGEN® may also receive approval in the future. In 2019, sales in the United States declined, and we expect them to continue to decline at a faster rate in 2020 due to short- and long-acting competition.

KYPROLIS®

Total KYPROLIS® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2019	Change	Year ended December 31, 2018	Change	Year ended December 31, 2017
KYPROLIS® — U.S.	$ 654	12 %	$ 583	4 %	$ 562
KYPROLIS® — ROW	390	1 %	385	41 %	273
Total KYPROLIS®	$ 1,044	8 %	$ 968	16 %	$ 835

The increase in global KYPROLIS® sales for 2019 was driven primarily by higher unit demand.

The increase in global KYPROLIS® sales for 2018 was driven primarily by higher unit demand, offset partially by lower net selling price.

We are engaged in litigation with two related companies that are challenging our material patents related to KYPROLIS® and that are seeking to market generic carfilzomib products. Separately, we have entered into confidential settlement agreements with other companies developing generic carfilzomib products, and the court has entered consent judgments enjoining those companies from infringing certain of our patents, subject to terms of the confidential settlement agreements. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. The FDA has reported that it has tentatively approved Abbreviated New Drug Applications (ANDAs) filed by two companies for generic carfilzomib products. The date of final approval of those ANDAs is governed by the Hatch-Waxman Act and any applicable settlement agreements between the parties.

EPOGEN®

Total EPOGEN® sales were as follows (dollar amounts in millions):

	Year ended December 31, 2019	Change	Year ended December 31, 2018	Change	Year ended December 31, 2017
EPOGEN® — U.S.	$ 867	(14 %)	$ 1,010	(8 %)	$ 1,096

The decreases in EPOGEN® sales for 2019 and 2018 were driven primarily by a decline in net selling price due to our contract with DaVita. See Part I, Item I. Business—Business Relationships. In 2020, we expect a lower net selling price compared with 2019 due to our contract with DaVita.

A biosimilar version of EPOGEN® has been approved and launched, and other biosimilar versions may also receive approval in the future. Therefore, we face increased competition in the United States, which has had and will continue to have a material adverse impact on sales of EPOGEN®. For a discussion of ongoing patent litigation related to one of these biosimilars, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Sensipar®/Mimpara®

Total Sensipar®/Mimpara® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2019	Change	Year ended December 31, 2018	Change	Year ended December 31, 2017
Sensipar® — U.S.	$ 252	(82)%	$ 1,436	5 %	$ 1,374
Sensipar®/Mimpara® — ROW	299	(12)%	338	(2)%	344
Total Sensipar®/Mimpara®	$ 551	(69)%	$ 1,774	3 %	$ 1,718

The decrease in global Sensipar®/Mimpara® sales for 2019 was driven by the impact of generic competitors on unit demand.

The increase in global Sensipar®/Mimpara® sales for 2018 was driven primarily by an increase in net selling price in the United States, offset partially by lower unit demand.

Our U.S. composition-of-matter patent related to Sensipar®, a small molecule, expired in March 2018. We are involved in litigation with a number of companies seeking to market generic cinacalcet products surrounding our U.S. formulation patent, which expires in September 2026. During the course of the patent litigation, we have entered into confidential settlement agreements with several of these companies. The court has entered consent judgments enjoining certain of those companies from infringing certain of our patents, subject to terms of the confidential settlement agreements. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. Companies manufacturing generics began selling their generic cinacalcet products in the United States in late 2018 and 2019. Sensipar® sales have been and, we believe, may continue to be adversely impacted as a result of generic-product sales in the U.S. market.

Other products

Other product sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2019	Change	Year ended December 31, 2018	Change	Year ended December 31, 2017
Nplate® — U.S.	$ 480	10 %	$ 438	12 %	$ 392
Nplate® — ROW	315	13 %	279	12 %	250
Vectibix® — U.S.	316	10 %	288	15 %	251
Vectibix® — ROW	428	6 %	403	3 %	391
Repatha® — U.S.	376	5 %	358	59 %	225
Repatha® — ROW	285	48 %	192	*	94
Parsabiv® — U.S.	550	82 %	302	*	—
Parsabiv® — ROW	80	*	34	*	5
BLINCYTO® — U.S.	176	31 %	134	18 %	114
BLINCYTO® — ROW	136	42 %	96	57 %	61
Aimovig® — U.S.	306	*	119	*	—
NEUPOGEN® — U.S.	178	(20 %)	223	(40 %)	369
NEUPOGEN® — ROW	86	(39 %)	142	(21 %)	180
KANJINTI™ — U.S.	118	*	—	— %	—
KANJINTI™ — ROW	108	*	44	*	—
AMGEVITA™ — ROW	215	*	11	*	—
EVENITY® — U.S.	42	*	—	— %	—
EVENITY® — ROW	147	*	—	— %	—
Otezla® — U.S.	139	*	—	— %	—
Otezla® — ROW	39	*	—	— %	—
MVASI™ — U.S.	121	*	—	— %	—
MVASI™ — ROW	6	*	—	— %	—
Other — U.S.	105	24 %	85	25 %	68
Other — ROW	207	9 %	190	4 %	183
Total other product sales	$ 4,959	49 %	$ 3,338	29 %	$ 2,583
Total U.S. — other products	$ 2,907	49 %	$ 1,947	37 %	$ 1,419
Total ROW — other products	2,052	48 %	1,391	20 %	1,164
Total other product sales	$ 4,959	49 %	$ 3,338	29 %	$ 2,583

* Change in excess of 100%.

Operating expenses

Operating expenses were as follows (dollar amounts in millions):

	Year ended December 31, 2019	Change	Year ended December 31, 2018	Change	Year ended December 31, 2017
Operating expenses:					
Cost of sales	$ 4,356	6 %	$ 4,101	1 %	$ 4,069
% of product sales	19.6 %		18.2 %		18.7 %
% of total revenues	18.6 %		17.3 %		17.8 %
Research and development	$ 4,116	10 %	$ 3,737	5 %	$ 3,562
% of product sales	18.5 %		16.6 %		16.3 %
% of total revenues	17.6 %		15.7 %		15.6 %
Selling, general and administrative	$ 5,150	(3 %)	$ 5,332	9 %	$ 4,870
% of product sales	23.2 %		23.7 %		22.3 %
% of total revenues	22.0 %		22.5 %		21.3 %
Other	$ 66	(79 %)	$ 314	(16 %)	$ 375

Cost of sales

Cost of sales increased to 18.6% of total revenues for 2019, driven primarily by unfavorable product mix and amortization of intangible assets as a result of our acquisition of Otezla®, offset partially by lower royalties and lower manufacturing costs.

Cost of sales decreased to 17.3% of total revenues for 2018, driven primarily by lower royalty costs, expenses related to Hurricane Maria in 2017 and lower acquisition-related amortization of intangible assets, offset partially by higher manufacturing costs.

Research and development

The Company groups all of its R&D activities and related expenditures into three categories: (i) research and early pipeline, (ii) later-stage clinical programs and (iii) marketed products. These categories are described below:

Category	Description
Research and early pipeline	R&D expenses incurred in activities substantially in support of early research through the completion of phase 1 clinical trials, including drug discovery, toxicology, pharmacokinetics and drug metabolism, and process development
Later-stage clinical programs	R&D expenses incurred in or related to phase 2 and phase 3 clinical programs intended to result in registration of a new product or a new indication for an existing product primarily in the United States or the EU
Marketed products	R&D expenses incurred in support of the Company's marketed products that are authorized to be sold primarily in the United States or the EU. Includes clinical trials designed to gather information on product safety (certain of which may be required by regulatory authorities) and their product characteristics after regulatory approval has been obtained, as well as the costs of obtaining regulatory approval of a product in a new market after approval in either the United States or the EU has been obtained

R&D expense by category was as follows (in millions):

	Years ended December 31,		
	2019	2018	2017
Research and early pipeline	$ 1,649	$ 1,201	$ 972
Later-stage clinical programs	1,062	1,034	879

Marketed products	1,405	1,502	1,711
Total R&D expense	$ 4,116	$ 3,737	$ 3,562

The increase in R&D expense for 2019 was driven primarily by higher spend in research and early pipeline in support of our oncology programs, offset partially by lower marketed-product support.

The increase in R&D expense for 2018 was driven by higher spend on our early pipeline and later-stage clinical programs as well as external business development expense in research and early pipeline, offset partially by lower marketed-product support.

Selling, general and administrative

The decrease in Selling, general and administrative (SG&A) expenses for 2019 was driven primarily by lower general and administrative expenses, the end of certain amortization charges in 2018 and lower spend for launched and marketed products, offset partially by spending for Otezla® commercial-related expenses.

The increase in SG&A expense for 2018 was driven primarily by investments in product launches and marketed-product support.

Other

Other operating expenses for 2019 included $47 million in restructuring costs.

Other operating expenses for 2018 included a $330 million impairment charge associated with an IPR&D asset and a $42 million favorable net change in the fair values of contingent consideration liabilities. See Part IV—Note 17, Fair value measurement, to the Consolidated Financial Statements.

Other operating expenses for 2017 included $284 million of impairment-related charges associated with an intangible asset acquired in a business combination and $83 million of certain net charges related to a restructuring plan.

Nonoperating expenses/income and income taxes

Nonoperating expenses/income and income taxes were as follows (dollar amounts in millions):

	Years ended December 31,		
	2019	2018	2017
Interest expense, net	$ 1,289	$ 1,392	$ 1,304
Interest and other income, net	$ 753	$ 674	$ 928
Provision for income taxes	$ 1,296	$ 1,151	$ 7,618
Effective tax rate	14.2 %	12.1 %	79.4 %

Interest expense, net

The decrease in Interest expense, net, for 2019 was due primarily to a reduction in outstanding long-term debt as a result of maturities in the current year.

The increase in Interest expense, net, for 2018 was due primarily to the impact of rising interest rates on variable-rate debt.

Interest and other income, net

The increase in Interest and other income, net, for 2019 was due primarily to net gains on sales of investments in interest-bearing securities liquidated to fund our acquisition of Otezla® and our investment in BeiGene compared with losses in the prior year, offset partially by reduced interest income as a result of lower average cash balances and a gain recognized in connection with our acquisition of Kirin-Amgen, Inc. (K-A), in the first quarter of 2018. See Part IV—Note 2, Acquisitions, and Note 21, Subsequent events, to the Consolidated Financial Statements.

The decrease in Interest and other income, net, for 2018 was due primarily to higher investment losses and lower interest income as a result of the liquidation of a portion of our portfolio, offset partially by gains on our equity investments and a net gain recognized in connection with our acquisition of K-A.

Income taxes

The increase in our effective tax rate for 2019 compared with 2018 was due primarily to a prior-year tax benefit associated with intercompany sales under U.S. corporate tax reform.

The decrease in our effective tax rate for 2018 compared with 2017 was due primarily to impacts of U.S. corporate tax reform.

As previously disclosed, we received an RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Final resolution of this complex matter is not likely within the next 12 months and could have a material impact on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments substantially greater or less than amounts accrued.

See Summary of Critical Accounting Policies—Income taxes, and Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

Financial Condition, Liquidity and Capital Resources

Selected financial data was as follows (in millions):

	December 31,	
	2019	2018
Cash, cash equivalents and marketable securities	$ 8,911	$ 29,304
Total assets	$ 59,707	$ 66,416
Current portion of long-term debt	$ 2,953	$ 4,419
Long-term debt	$ 26,950	$ 29,510
Stockholders' equity	$ 9,673	$ 12,500

Cash, cash equivalents and marketable securities

We have global access to our $8.9 billion balance of cash, cash equivalents and marketable securities. The primary objective of our investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

Capital allocation

Consistent with the objective to optimize our capital structure, we seek to deploy our accumulated cash balances in an efficient manner, and we consider several alternatives such as payment of dividends, stock repurchases, repayment of debt and strategic transactions that expand our portfolio of products in areas of therapeutic interest.

We intend to continue to invest in our business while returning capital to stockholders through the payment of cash dividends and stock repurchases, thereby reflecting our confidence in the future cash flows of our business. The timing and amount of future dividends and stock repurchases will vary based on a number of factors, including future capital requirements for strategic transactions, availability of financing on acceptable terms, debt service requirements, our credit rating, changes to applicable tax laws or corporate laws, changes to our business model and periodic determination by our Board of Directors that cash dividends and/or stock repurchases are in the best interests of stockholders and are in compliance with applicable laws and the Company's agreements. In addition, the timing and amount of stock repurchases may also be affected by stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include private block purchases, tender offers and market transactions.

The Board of Directors declared quarterly cash dividends of $1.15 per share of common stock paid in 2017, increased our quarterly cash dividend by 15% to $1.32 per share of common stock paid in 2018 and increased our quarterly cash dividend by 10% to $1.45 per share of common stock paid in 2019. In December 2019, the Board of Directors declared a cash dividend of $1.60 per share of common stock for the first quarter of 2020, an increase of 10% for this period, to be paid in March 2020.

We also returned capital to stockholders through our stock repurchase program. During 2019, we repurchased $7.6 billion of common stock and had cash settlements of $7.7 billion. In 2018, we repurchased $17.9 billion of common stock and had cash settlements of $17.8 billion, which included 52.1 million shares of common stock repurchased through a $10.0 billion tender offer. In 2017, we repurchased $3.1 billion of common stock and had cash settlements of $3.2 billion. In May 2019 and December 2019,

our Board of Directors increased the amount authorized under our stock repurchase program by an additional $5.0 billion and $4.0 billion, respectively. As of December 31, 2019, $6.5 billion remained available under the stock repurchase program.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of December 31, 2019 and 2018. Our accumulated deficit is not expected to affect our future ability to operate, repurchase stock, pay dividends or repay our debt given our continuing profitability and strong financial position.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital, capital expenditure and debt service requirements, our plans to pay dividends and repurchase stock and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt markets and equity markets. See Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business*.

Financing arrangements

The current and noncurrent portions of our long-term borrowings as of December 31, 2019, were $3.0 billion and $27.0 billion, respectively. The current and noncurrent portions of our long-term borrowings as of December 31, 2018, were $4.4 billion and $29.5 billion, respectively. As of December 31, 2019, Standard & Poor's Financial Services LLC (S&P), Moody's Investors Service, Inc. (Moody's), and Fitch Ratings, Inc. (Fitch), assigned credit ratings to our outstanding senior notes of A- with a stable outlook, Baa1 with a stable outlook and BBB+ with a stable outlook, respectively, which are considered investment grade. Unfavorable changes to these ratings may have an adverse impact on future financings.

During 2019 and 2018, we did not issue any debt or debt securities. During 2017, we issued debt with an aggregate principal amount of $4.5 billion. During 2019, 2018 and 2017, we repaid debt of $4.5 billion, $1.1 billion and $4.4 billion, respectively.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the life of the respective note. These interest rate swap contracts qualify and are designated as fair value hedges. As of December 31, 2019 and 2018, we had interest rate swap contracts with aggregate notional amounts of $9.6 billion and $11.0 billion, respectively.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts, which effectively convert the interest payments and principal repayment of the respective notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts qualify and are designated as cash flow hedges. As of December 31, 2019 and 2018, we had cross-currency swap contracts with aggregate notional amounts of $4.8 billion and $5.6 billion, respectively.

As of December 31, 2019, we had a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. During 2017, we issued and repaid an aggregate of $12.3 billion of commercial paper and had a maximum outstanding balance of $1.5 billion under our commercial paper program. During 2019 and 2018, we did not issue any commercial paper. No commercial paper was outstanding as of December 31, 2019 or 2018.

In 2019, we amended and restated our $2.5 billion syndicated, unsecured, revolving credit agreement, which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $750 million with the agreement of the banks. Each bank that is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest for any amounts borrowed under this facility, based on our current credit rating, at (i) LIBOR plus 1% or (ii) the highest of (A) the syndication agent bank base commercial lending rate, (B) the overnight federal funds rate plus 0.50% or (C) one-month LIBOR plus 1%. The agreement contains provisions relating to the determination of successor rates to address the possible phase-out or unavailability of designated reference rates. As of December 31, 2019 and 2018, no amounts were outstanding under this facility.

It is anticipated that LIBOR will be phased out and replaced by 2022. While various replacement reference rates have been discussed, an alternative reference rate to LIBOR has not yet been widely adopted. Therefore, the mechanics to modify existing contracts that reference LIBOR have not been finalized. However, we do not expect that a change in the reference rate of our contracts will be material. See Part 1, Item 1A. Risk Factors—*Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.*

In February 2020, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2023.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which requires that we maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2019.

See Part IV—Note 15, Financing arrangements, and Note 18, Derivative instruments, to the Consolidated Financial Statements.

Cash flows

Our summarized cash flow activity was as follows (in millions):

	Years ended December 31,		
	2019	2018	2017
Net cash provided by operating activities	$ 9,150	$ 11,296	$ 11,177
Net cash provided by (used in) investing activities	$ 5,709	$ 14,339	$ (4,024)
Net cash used in financing activities	$ (15,767)	$ (22,490)	$ (6,594)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities decreased during 2019 due primarily to changes in working capital, an increase in payments to the IRS related to an advance deposit and lower Net income. Cash provided by operating activities increased during 2018 due primarily to improvements in working capital, offset partially by higher payments to tax authorities.

Investing

Cash provided by investing activities during 2019 and 2018 was due primarily to net cash inflows related to marketable securities of $20.0 billion and $15.0 billion, respectively. The liquidation of portions of our marketable securities portfolio in 2019 was due primarily to fund the acquisition of Otezla® and our investment in BeiGene and, in 2018, to fund the tender offer to repurchase our common stock. Cash used in investing activities during 2017 was due primarily to net cash outflows related to marketable securities of $3.2 billion. Capital expenditures were $618 million, $738 million and $664 million in 2019, 2018 and 2017, respectively. We currently estimate 2020 spending on capital projects to be approximately $700 million.

Financing

Cash used in financing activities during 2019 was due primarily to repurchases of our common stock of $7.7 billion, repayments of debt of $4.5 billion and payments of dividends of $3.5 billion. Cash used in financing activities during 2018 was due primarily to repurchases of our common stock of $17.8 billion, payments of dividends of $3.5 billion and repayments of debt of $1.1 billion. Cash used in financing activities during 2017 was due primarily to payments of dividends of $3.4 billion and repurchases of common stock of $3.2 billion, offset partially by proceeds from issuances of debt, net of repayments, of $71 million.

See Part IV—Note 15, Financing arrangements, and Note 16, Stockholders' equity, to the Consolidated Financial Statements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are material or reasonably likely to become material to our consolidated financial position or consolidated results of operations.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent liabilities for which we cannot reasonably predict future payment. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information. Timing of payments and actual amounts paid may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations.

The following table represents our contractual obligations aggregated by type (in millions):

	Payments due by period as of December 31, 2019				
Contractual obligations	**Total**	**Year 1**	**Years 2 and 3**	**Years 4 and 5**	**Years 6 and beyond**
Long-term debt obligations (1) (2) (3)	$ 48,080	$ 4,086	$ 9,612	$ 4,467	$ 29,915
Operating lease obligations (4)	910	159	266	157	328
Purchase obligations (5)	1,938	1,512	255	100	71
U.S. repatriation tax (6)	6,162	587	1,174	2,567	1,834
Unrecognized tax benefits (UTBs) (7)	—	—	—	—	—
Total contractual obligations	$ 57,090	$ 6,344	$ 11,307	$ 7,291	$ 32,148

(1) Long-term debt obligations include future interest payments on our fixed-rate obligations at the contractual coupon rates. To achieve a desired mix of fixed-rate and floating-rate debt, we enter into interest rate swap contracts that effectively convert a fixed-rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the terms of the related hedge contracts. We used an interest rate forward curve as of December 31, 2019, in computing net amounts to be paid or received under our interest rate swap contracts, which resulted in an aggregate net decrease in future interest payments of $309 million. See Part IV —Note 15, Financing arrangements, to the Consolidated Financial Statements.

(2) Long-term debt obligations include future interest payments on our LIBOR-based variable-rate obligations. We used an interest rate forward curve as of December 31, 2019, in computing the LIBOR-based portion of interest payments on these debt obligations. See Part IV—Note 15, Financing arrangements, to the Consolidated Financial Statements.

(3) Long-term debt obligations include contractual interest payments and principal repayments of our foreign-denominated debt obligations. In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our euro-, pound-sterling- and Swiss-franc-denominated long-term debt, we entered into cross-currency swap contracts that effectively converted interest payments and principal repayments on this debt from euros, pounds sterling and Swiss francs to U.S. dollars. For purposes of this table, we used the contracted exchange rates in the cross-currency swap contracts to compute the net amounts of future interest payments and principal repayments on this debt. See Part IV—Note 18, Derivative instruments, to the Consolidated Financial Statements.

(4) Operating lease obligations includes payments for leases that have not yet commenced, net of lease incentives, and excludes $141 million of future receipts under noncancelable subleases of abandoned facilities.

(5) Purchase obligations relate primarily to (i) R&D commitments (including those related to clinical trials) for new and existing products, (ii) capital expenditures and (iii) open purchase orders for the acquisition of goods and services in the ordinary course of business. Our obligation to pay certain of these amounts may be reduced based on certain future events.

(6) Under the 2017 Tax Act, we elected to pay in eight annual installments the repatriation tax related primarily to our prior indefinitely invested earnings of our foreign operations. See Part IV—Note 19, Contingencies and commitments—Commitments – U.S. repatriation tax, to the Consolidated Financial Statements.

(7)

Liabilities for UTBs are not included in the table above because due to their nature there is a high degree of uncertainty regarding the timing of future cash outflows and other events that extinguish these liabilities. See Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

In addition to amounts in the table above, we are contractually obligated to pay additional amounts, which in the aggregate are significant, upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties, including contingent consideration incurred in the acquisitions of K-A and BioVex Group Inc. (BioVex). These payments are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring. These contingent payments have not been included in the table above, and except with respect to the fair value of the contingent consideration obligations, are not recorded on our Consolidated Balance Sheets. As of December 31, 2019, the maximum amount that may be payable in the future for agreements we have entered into with third parties is $7.3 billion, including $325 million of contingent consideration payments in connection with the acquisition of BioVex. Contingent

consideration with respect to the acquisition of Dezima Pharma B.V. was excluded due to the discontinuation of the development of AMG 899, upon which payments are based. See Part IV—Note 17, Fair value measurement, to the Consolidated Financial Statements.

Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate. Accruals are also adjusted to reflect actual results. Amounts recorded in Accrued liabilities in the Consolidated Balance Sheets for sales deductions were as follows (in millions):

	Rebates	Chargebacks	Other deductions	Total
Balance as of December 31, 2016	$ 1,417	$ 342	$ 115	$ 1,874
Amounts charged against product sales	4,909	6,098	992	11,999
Payments	(4,459)	(6,168)	(999)	(11,626)
Balance as of December 31, 2017	1,867	272	108	2,247
Amounts charged against product sales	6,180	6,926	1,180	14,286
Payments	(5,458)	(6,744)	(1,161)	(13,363)
Balance as of December 31, 2018	2,589	454	127	3,170
Amounts charged against product sales	6,825	7,090	1,292	15,207
Payments	(6,249)	(6,985)	(1,263)	(14,497)
Balance as of December 31, 2019	$ 3,165	$ 559	$ 156	$ 3,880

For the years ended December 31, 2019, 2018 and 2017, total sales deductions were 41%, 39% and 35% of gross product sales, respectively. The increase in the total sales deductions balance as of December 31, 2019 compared to December 31, 2018, was driven primarily by the impact of increases in U.S. rebates and to a lesser extent, higher chargebacks. Included in the amounts are immaterial net adjustments related to prior-year sales due to changes in estimates. Such amounts represent less than 1% of the aggregate sales deductions charged against product sales in the years ended December 31, 2019, 2018 and 2017.

In the United States, we utilize wholesalers as the principal means of distributing our products to healthcare providers such as physicians or their clinics, dialysis centers, hospitals and pharmacies. Products we sell in Europe are distributed principally to hospitals and/or wholesalers depending on the distribution practice in each country where the products are sold. We monitor the inventory levels of our products at our wholesalers by using data from our wholesalers and other third parties, and we believe wholesaler inventories have been maintained at appropriate levels (generally two to three weeks) given end-user demand. Accordingly, historical fluctuations in wholesaler inventory levels have not significantly affected our method of estimating sales deductions and returns.

Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given year, can be affected by the mix of products sold.

Rebates include primarily amounts paid to payers and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements, which vary by product, by payer and by individual payer plans. As we sell products, we estimate the amount of rebate we will pay

based on the product sold, contractual terms, estimated patient population, historical experience and wholesaler inventory levels; and we accrue these rebates in the period the related sales are recorded. We then adjust the rebate accruals as more information becomes available and to reflect actual claims experience. Estimating such rebates is complicated, in part because of the time delay between the date of sale and the actual

settlement of the liability. We believe the methodology we use to accrue for rebates is reasonable and appropriate given current facts and circumstances, but actual results may differ.

Wholesaler chargebacks relate to our contractual agreements to sell products to healthcare providers in the United States at fixed prices that are lower than the prices we charge wholesalers. When healthcare providers purchase our products through wholesalers at these reduced prices, wholesalers charge us for the difference between their purchase prices and the contractual prices between Amgen and the healthcare providers. The provision for chargebacks is based on the expected sales by our wholesaler customers to healthcare providers. Accruals for wholesaler chargebacks are less difficult to estimate than rebates are, and they closely approximate actual results since chargeback amounts are fixed at the date of purchase by the healthcare providers and because we generally settle the liability for these deductions within a few weeks.

Product returns

Returns are estimated through comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. In each of the past three years, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-year sales return provisions have historically been immaterial.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is measured based on the largest benefit that is more likely than not to be realized. The amount of UTBs is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the tax authorities, new information obtained during a tax examination or resolution of an examination. We believe our estimates for uncertain tax positions are appropriate and sufficient for any assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense.

Certain items are included in our tax return at different times than they are reflected in the financial statements and cause temporary differences between the tax bases of assets and liabilities and their reported amounts. Such temporary differences create deferred tax assets and liabilities. Deferred tax assets are generally items that can be used as a tax deduction or credit in the tax return in future years but for which we have already recorded the tax benefit in the consolidated financial statements. We establish valuation allowances against our deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities are either (i) tax expenses recognized in the consolidated financial statements for which payment has been deferred, (ii) expenses for which we have already taken a deduction on the tax return but have not yet recognized in the consolidated financial statements or (iii) liabilities for the difference between the book basis and tax basis of the intangible assets acquired in many business combinations, as future expenses associated with these assets most often will not be tax deductible.

We are a vertically-integrated enterprise with operations in the United States and various foreign jurisdictions. We are subject to income tax in the foreign jurisdictions where we conduct operations based on the tax laws and principles of such jurisdictions and the functions, risks and activities performed therein. Our pretax income is therefore attributed to domestic or foreign sources based on the operations performed and risks assumed in each location and the tax laws and principles of the respective taxing jurisdictions. For example, we conduct significant operations in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes, pertaining to manufacturing, distribution and other related functions to meet our worldwide product demand. Income from our operations in Puerto Rico is subject to tax incentive grants through 2035.

As previously disclosed, we received an RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial

process. Final resolution of this complex matter is not likely within the next 12 months and could have a material impact on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments substantially greater or less than amounts accrued. See Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

Our operations are subject to the tax laws, regulations and administrative practices of the United States, U.S. state jurisdictions and other countries, including the U.S. territory of Puerto Rico, in which we do business. Significant changes in these rules could have a material adverse effect on our results of operations. See Part I, Item 1A. Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability*.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters such as intellectual property disputes, contractual disputes and class action suits which are complex in nature and have outcomes that are difficult to predict. We describe our legal proceedings and other matters that are significant or that we believe could become significant in Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Valuation of assets and liabilities in connection with acquisitions

We have acquired and continue to acquire intangible assets in connection with business combinations and asset acquisitions. These intangible assets consist primarily of technology associated with currently marketed human therapeutic products and IPR&D product candidates. Discounted cash flow models are typically used to determine the fair values of these intangible assets for purposes of allocating consideration paid to the net assets acquired in an acquisition. See Part IV—Note 2, Acquisitions, to the Consolidated Financial Statements. These models require the use of significant estimates and assumptions, including but not limited to:

- determining the timing and expected costs to complete in-process projects, taking into account the stage of completion at the acquisition date;
- projecting the probability and timing of obtaining marketing approval from the FDA and other regulatory agencies for product candidates;
- estimating the timing of and future net cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates to calculate the present values of the cash flows.

Significant estimates and assumptions are also required to determine the business combination date fair values of any contingent consideration obligations incurred in connection with business combinations. In addition, we must revalue these obligations each subsequent reporting period until the related contingencies are resolved and record changes in their fair values in earnings. The acquisition date fair values of contingent consideration obligations incurred or assumed in the acquisitions were determined using a combination of valuation techniques. Significant estimates and assumptions required for these valuations included but were not limited to the probability of achieving regulatory milestones, product sales projections under various scenarios and discount rates used to calculate the present value of the required payments. These estimates and assumptions are required to be updated in order to revalue these contingent consideration obligations each reporting period. Accordingly, subsequent changes in underlying facts and circumstances could result in changes in these estimates and assumptions, which could have a material impact on the estimated future fair values of these obligations.

We believe the fair values used to record intangible assets acquired and contingent consideration obligations incurred in connection with business combinations and assets acquisitions are based on reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Impairment of long-lived assets

We review the carrying value of our property, plant and equipment and our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows to be generated by the long-lived asset is compared to the carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value.

Indefinite-lived intangible assets, composed of IPR&D projects acquired in a business combination that have not reached technological feasibility or that lack regulatory approval at the time of acquisition, are reviewed for impairment annually, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon establishment of technological feasibility or regulatory approval. We determine impairment by comparing the fair value of the asset to its carrying value. If the asset's carrying value exceeds its fair value, an impairment charge is recorded for the difference, and its carrying value is reduced accordingly.

Estimating future cash flows of an IPR&D product candidate for purposes of an impairment analysis requires us to make significant estimates and assumptions regarding the amount and timing of costs to complete the project and the amount, timing and probability of achieving revenues from the completed product similar to how the acquisition date fair value of the project was determined, as described above. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market these products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods which could have a material adverse effect on our results of operations.

We believe our estimations of future cash flows used for assessing impairment of long-lived assets are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

Recently Issued Accounting Standards

See Part IV—Note 1, Summary of significant accounting policies, to the Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 31, 2019.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks that may result from changes in interest rates, foreign currency exchange rates and prices of equity instruments as well as changes in general economic conditions in the countries where we conduct business. To reduce certain of these risks, we enter into various types of foreign currency and interest rate derivative hedging transactions as part of our risk management program. We do not use derivatives for speculative trading purposes.

In the discussion that follows, we have assumed a hypothetical change in interest rates of 100 basis points from those as of December 31, 2019 and 2018. Except as noted below, we have also assumed a hypothetical 20% change in foreign currency exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2019 and 2018.

Interest-rate-sensitive financial instruments

Our portfolio of available-for-sale investments as of December 31, 2019 and 2018, was composed of U.S. Treasury securities, corporate debt securities, residential-mortgage-backed and other mortgage- and asset-backed securities, money market mutual funds and other short-term interest-bearing securities composed principally of commercial paper, and with respect to investments as of December 31, 2018, other government-related securities. The fair values of our available-for-sale investments were $8.2 billion and $28.7 billion as of December 31, 2019 and 2018, respectively. Duration is a sensitivity measure that can be used to approximate the change in the value of a security that will result from a 100 basis point change in interest rates. Applying a duration model, a hypothetical 100 basis point increase in interest rates as of December 31, 2019, would not have resulted in a material reduction in the fair value of these securities, and with respect to available-for-sale securities as of December 31, 2018, would have resulted in a reduction of approximately $360 million in fair value. In addition, a hypothetical 100 basis point decrease in interest rates as of December 31, 2019 and 2018, would not result in a material effect on income in the respective ensuing year.

As of December 31, 2019, we had outstanding debt with a carrying value of $29.9 billion and a fair value of $33.7 billion. As of December 31, 2018, we had outstanding debt with a carrying value of $33.9 billion and a fair value of $35.0 billion. Our outstanding debt was composed primarily of debt with fixed interest rates, with variable-rate debt having carrying values of $300 million and $850 million as of December 31, 2019 and 2018, respectively. Changes in interest rates do not affect interest expense on fixed-rate debt. Changes in interest rates would, however, affect the fair values of fixed-rate debt. A hypothetical 100 basis

point decrease in interest rates relative to interest rates as of December 31, 2019 and 2018, would have resulted in increases of $3.0 billion and $2.6 billion, respectively, in the aggregate fair value of our outstanding debt on each of these dates. Analysis of the debt does not consider the impact that hypothetical changes in interest rates would have on the related interest rate swap contracts and cross-currency swap contracts, discussed below.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified and were designated for accounting purposes as fair value hedges for certain of our fixed-rate debt. These interest rate swap contracts effectively converted a fixed-rate interest coupon to a floating-rate LIBOR-based coupon over the life of the respective note. Interest rate swap contracts with aggregate notional amounts of $9.6 billion and $11.0 billion were outstanding as of December 31, 2019 and 2018, respectively. A hypothetical 100 basis point increase in interest rates relative to interest rates as of December 31, 2019 and 2018, would have resulted in reductions in fair values of approximately $380 million and $460 million, respectively, on our interest rate swap contracts on these dates and would not result in a material effect on the related income in the respective ensuing years. Analysis of the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair values of debt that these interest-rate-sensitive instruments were designed to offset.

As of December 31, 2019 and 2018, we had outstanding cross-currency swap contracts with aggregate notional amounts of $4.8 billion and $5.6 billion, respectively, that hedge our foreign-currency-denominated debt and related interest payments. These contracts effectively convert interest payments and principal repayment of this debt to U.S. dollars from euros, pounds sterling and Swiss francs and are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates as of December 31, 2019 and 2018, would have resulted in reductions in the fair values of our cross-currency swap contracts of approximately $280 million and $320 million, respectively.

Foreign-currency-sensitive financial instruments

Our international operations are affected by fluctuations in the value of the U.S. dollar as compared to foreign currencies, predominantly the euro. Increases and decreases in our international product sales from movements in foreign currency exchange rates are offset partially by the corresponding increases or decreases in our international operating expenses. Increases and decreases in our foreign-currency-denominated assets from movements in foreign currency exchange rates are offset partially by the corresponding increases or decreases in our foreign-currency-denominated liabilities. To further reduce our net exposure to foreign currency exchange rate fluctuations on our results of operations, we enter into foreign currency forward, option and cross-currency swap contracts.

As of December 31, 2019, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and a fair value of $4.5 billion and $5.0 billion, respectively. As of December 31, 2018, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and a fair value of $5.3 billion and $5.6 billion, respectively. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2019, would have resulted in an increase in fair value of this debt of $1.0 billion on this date and a reduction in income in the ensuing year of $0.9 billion. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2018, would have resulted in an increase in fair value of this debt of $1.1 billion on this date and a reduction in income in the ensuing year of $1.1 billion. The impact on income from these hypothetical changes in foreign currency exchange rates would be substantially offset by the impact such changes would have on related cross-currency swap contracts, which are in place for the related foreign-currency-denominated debt.

We have cross-currency swap contracts that are designated as cash flow hedges of our debt denominated in euros, pounds sterling and Swiss francs with aggregate notional amounts of $4.8 billion and $5.6 billion as of December 31, 2019 and 2018, respectively. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would have resulted in reductions in the fair values of these contracts of $1.0 billion and $1.2 billion on these dates, respectively. The impact of this hypothetical adverse movement in foreign currency exchange rates on ensuing years' income from these contracts would be fully offset by the corresponding hypothetical changes in the carrying amounts of the related hedged debt.

We enter into foreign currency forward and options contracts that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2019, we had primarily euro based open foreign currency forward contracts with notional amounts of $5.0 billion. As of December 31, 2018, we had primarily euro based open foreign currency forward and option contracts with notional amounts of $4.5 billion and $21 million, respectively. As of December 31, 2019, the fair values of these contracts were a $223 million

asset and a $31 million liability. As of December 31, 2018, the fair values of these contracts were a $181 million asset and a $26 million liability. With regard to foreign currency forward and option contracts that were open as of December 31, 2019, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2019, would have resulted in a reduction in fair value of these contracts of approximately $930 million on this date and, in the ensuing year, a reduction in income of approximately $400 million. With regard to contracts that were open as of December 31, 2018, a hypothetical 20% adverse movement in foreign

currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2018, would have resulted in a reduction in fair value of these contracts of $810 million on this date and, in the ensuing year, a reduction in income of $380 million. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign-currency-sensitive instruments were designed to offset.

As of December 31, 2019 and 2018, we had open short-duration foreign currency forward contracts that mature in less than one month with notional amounts of $1.2 billion and $737 million, respectively, that hedged fluctuations of certain assets and liabilities denominated in foreign currencies but were not designated as hedges for accounting purposes. These contracts had no material net unrealized gains or losses as of December 31, 2019 and 2018. With regard to these foreign currency forward contracts that were open as of December 31, 2019 and 2018, a hypothetical 5% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would not have a material effect on the fair values of these contracts or related income in the respective ensuing years. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on assets and liabilities that these foreign-currency-sensitive instruments were designed to offset.

Market-price-sensitive financial instruments

As of December 31, 2019 and 2018, we were exposed to price risk on equity securities included in our portfolio of investments, which were acquired primarily for the promotion of business and strategic objectives. These investments are generally in small-capitalization stocks in the biotechnology industry sector. Price risk relative to our equity investment portfolio as of December 31, 2019 and 2018, was not material.

Counterparty credit risks

Our financial instruments, including derivatives, are subject to counterparty credit risk, which we consider as part of the overall fair value measurement. Our financial risk management policy limits derivative transactions by requiring that transactions be made only with institutions with minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch; and it requires placing exposure limits on the amount with any individual counterparty. In addition, we have an investment policy that limits investments to certain types of debt and money market instruments issued by institutions primarily with investment-grade credit ratings and places restriction on maturities and concentrations by asset class and issuer.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is incorporated herein by reference to the financial statements and schedule listed in Item 15(a)1 and (a)2 of Part IV and included in this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under the Securities Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance Amgen's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2019.

Management determined that, as of December 31, 2019, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States. However, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and reporting.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our assessment, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

Management excluded Otezla®, which was acquired by us on November 21, 2019, from its assessment of internal control over financial reporting as of December 31, 2019. Total assets and revenues of Otezla® excluded from our assessment of internal control over financial reporting were approximately 0.6% of total assets and 0.8% of total revenues as of and for the period ended December 31, 2019.

The effectiveness of the Company's internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing below, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2019.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Amgen Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Amgen Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Amgen Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

As indicated in the accompanying Management's Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of the worldwide rights to Otezla® acquired from Celgene Corporation, which is included in the 2019 consolidated financial statements of the Company and constituted 0.6% of total assets, as of December 31, 2019 and 0.8% of revenues, for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of the worldwide rights to Otezla® acquired from Celgene Corporation.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of income, comprehensive income, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and schedule and our report dated February 12, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that

controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Los Angeles, California

February 12, 2020

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about our Directors is incorporated by reference from the section entitled ITEM 1—ELECTION OF DIRECTORS in our Proxy Statement for the 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2019 (the Proxy Statement). Information about the procedures by which stockholders may recommend nominees for the Board of Directors is incorporated by reference from APPENDIX A —AMGEN INC. BOARD OF DIRECTORS GUIDELINES FOR DIRECTOR QUALIFICATIONS AND EVALUATIONS and OTHER MATTERS—Stockholder Proposals for the 2021 Annual Meeting in our Proxy Statement. Information about our Audit Committee, members of the committee and our Audit Committee financial experts is incorporated by reference from the section entitled CORPORATE GOVERNANCE—Audit Committee in our Proxy Statement. Information about our executive officers is contained in the discussion entitled Part I—Item 1. Business—Information about our Executive Officers.

Code of Ethics

We maintain a Code of Ethics for the Chief Executive Officer and Senior Financial Officers applicable to our principal executive officer, principal financial officer, principal accounting officer or controller, and other persons performing similar functions. To view this code of ethics free of charge, please visit our website at www.amgen.com. (This website address is not intended to function as a hyperlink, and the information contained in our website is not intended to be a part of this filing.) We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics, if any, by posting such information on our website as set forth above.

Item 11. EXECUTIVE COMPENSATION

Information about director and executive compensation is incorporated by reference from the section entitled EXECUTIVE COMPENSATION in our Proxy Statement. Information about compensation committee matters is incorporated by reference from the sections entitled CORPORATE GOVERNANCE—Compensation and Management Development Committee and CORPORATE GOVERNANCE—Compensation Committee Report in our Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table sets forth certain information as of December 31, 2019, concerning the shares of our common stock that may be issued under any form of award granted under our equity compensation plans in effect as of December 31, 2019 (including upon the exercise of options, upon the vesting of awards of restricted stock units (RSUs) or when performance units are earned and related dividend equivalents have been granted).

Plan category	(a) Number of securities to be issued upon exercise of outstanding options and rights	(b) Weighted-average exercise price of outstanding options and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by Amgen security holders:			
Amended and Restated 2009 Equity Incentive Plan[1]	10,233,680	$ 157.00	27,552,603
Amended and Restated 1991 Equity Incentive Plan[2]	13,439	—	—
Amended and Restated Employee Stock Purchase Plan	—	—	4,506,117
Total approved plans	10,247,119	157.00	32,058,720
Equity compensation plan not approved by Amgen security holders:			
Amgen Profit Sharing Plan for Employees in Ireland[3]	—	—	78,057
Total unapproved plans	—	—	78,057
Total all plans	10,247,119	$ 157.00	32,136,777

(1) The Amended and Restated 2009 Equity Incentive Plan employs a fungible share-counting formula for determining the number of shares available for issuance under the plan. In accordance with this formula, each option or stock appreciation right counts as one share, while each restricted stock unit, performance unit or dividend equivalent counts as 1.9 shares. The number under column (a) represents the actual number of shares issuable under our outstanding awards without giving effect to the fungible share-counting formula. The number under column (c) represents the number of shares available for issuance under this plan based on each such available share counting as one share. Commencing with the grants made in April 2012, RSUs and performance units accrue dividend equivalents that are payable in shares only to the extent and when the underlying RSUs vest or underlying performance units have been earned and the related shares are issued to the grantee. The performance units granted under this plan are earned based on the accomplishment of specified performance goals at the end of their respective three-year performance periods; the number of performance units granted represent target performance, and the maximum number of units that could be earned based on our performance is 200% of the performance units granted in 2017, 2018 and 2019.

As of December 31, 2019, the number of outstanding awards under column (a) includes (i) 4,823,162 shares issuable upon the exercise of outstanding options with a weighted-average exercise price of $157.00; (ii) 3,324,005 shares issuable upon the vesting of outstanding RSUs (including 180,878 related dividend equivalents); and (iii) 2,086,513 shares subject to outstanding 2017, 2018 and 2019 performance units (including 97,836 related dividend equivalents). The weighted-average exercise price shown in column (b) is for the outstanding options only. The number of available shares under column (c) represents the number of shares that remain available for future issuance under this plan as of December 31, 2019, employing the fungible share formula and presumes the issuance of target shares under the performance units granted in 2017, 2018 and 2019 and related dividend equivalents. The numbers under columns (a) and (c) do not give effect to the additional shares that could be issuable in the event above target performance on the performance goals

under these outstanding performance units is achieved. Maximum performance under these goals could result in 200% of target shares being awarded for performance units granted in 2017, 2018 and 2019.

(2) This plan has terminated as to future grants. The number under column (a) with respect to this plan includes 13,439 shares issuable upon the settlement of deferred RSUs (including 2,357 related dividend equivalents).

(3) The Amgen Profit Sharing Plan for Employees in Ireland (the Profit Sharing Plan) was approved by the Board of Directors on July 28, 2011. The Profit Sharing Plan permits eligible employees of the Company's subsidiaries located in Ireland who participate in the Profit Sharing Plan to apply a portion of their qualifying bonus and salary to the purchase the Company's common stock on the open market at the market price by a third-party trustee as described in the Profit Sharing Plan.

Security Ownership of Directors and Executive Officers and Certain Beneficial Owners

Information about security ownership of certain beneficial owners and management is incorporated by reference from the sections entitled SECURITY OWNERSHIP OF DIRECTORS AND EXECUTIVE OFFICERS and SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS in our Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information about certain relationships and related transactions and director independence is incorporated by reference from the sections entitled CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS and CORPORATE GOVERNANCE—Director Independence in our Proxy Statement.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information about the fees for professional services rendered by our independent registered public accountants is incorporated by reference from the section entitled AUDIT MATTERS—Independent Registered Public Accountants in our Proxy Statement.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)1. Index to Financial Statements

The following Consolidated Financial Statements are included herein:

	Page number
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Statements of Income for each of the three years in the period ended December 31, 2019	F-4
Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2019	F-5
Consolidated Balance Sheets as of December 31, 2019 and 2018	F-6
Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2019	F-7
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2019	F-8
Notes to Consolidated Financial Statements	F-9

(a)2. Index to Financial Statement Schedules

The following Schedule is filed as part of this Annual Report on Form 10-K:

	Page number
II. Valuation and Qualifying Accounts	F-60

All other schedules are omitted because they are not applicable, not required or because the required information is included in the consolidated financial statements or notes thereto.

(a)3. Exhibits

Exhibit No.	Description
2.1	Asset Purchase Agreement, dated August 25, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.2	Amendment No. 1 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on October 17, 2019 and incorporated herein by reference.)
2.3*	Amendment No. 2 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation.
2.4*	Letter Agreement, dated November 21, 2019, by and between Amgen Inc. and the parties named therein re: Treatment of Certain Product Inventory in connection with Amgen's acquisition of Otezla®
2.5	Irrevocable Guarantee, dated August 25, 2019, by and between Amgen Inc. and Bristol-Myers Squibb Company. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)

3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)

4.2 Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)

4.3 Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)

4.4 First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)

4.5 8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)

4.6 Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)

4.7 Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)

4.8 Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)

4.9 Officers' Certificate of Amgen Inc., dated May 30, 2007, including form of the Company's 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)

4.10 Officers' Certificate of Amgen Inc., dated May 23, 2008, including form of the Company's 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)

4.11 Officers' Certificate of Amgen Inc., dated January 16, 2009, including form of the Company's 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)

4.12 Officers' Certificate of Amgen Inc., dated March 12, 2010, including forms of the Company's 4.50% Senior Notes due 2020 and 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.)

4.13 Officers' Certificate of Amgen Inc., dated September 16, 2010, including forms of the Company's 3.45% Senior Notes due 2020 and 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)

4.14 Officers' Certificate of Amgen Inc., dated June 30, 2011, including forms of the Company's 4.10% Senior Notes due 2021 and 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)

4.15 Officers' Certificate of Amgen Inc., dated November 10, 2011, including forms of the Company's 3.875% Senior Notes due 2021 and 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)

4.16 Officers' Certificate of Amgen Inc., dated December 5, 2011, including form of the Company's 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)

4.17 Officers' Certificate of Amgen Inc., dated May 15, 2012, including forms of the Company's 3.625% Senior Notes due 2022 and 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)

4.18

Officers' Certificate of Amgen Inc., dated September 13, 2012, including form of the Company's 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)

4.19 Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)

4.20 Officers' Certificate of Amgen Inc., dated May 22, 2014, including form of the Company's 3.625% Senior Notes due 2024. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)

4.21 Officer's Certificate of Amgen Inc., dated May 1, 2015, including forms of the Company's 2.125% Senior Notes due 2020, 2.700% Senior Notes due 2022, 3.125% Senior Notes due 2025 and 4.400% Senior Notes due 2045. (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.)

4.22	Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including forms of the Company's 1.250% Senior Notes due 2022 and 2.000% Senior Notes due 2026. (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.)
4.23	Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.24	Terms of the Bonds for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.25	Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.26	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 1.850% Senior Notes due 2021, 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of May 11, 2017 including forms of the Company's Senior Floating Rate Notes due 2020, 2.200% Senior Notes due 2020 and 2.650% Senior Notes due 2022. (Filed as an exhibit to Form 8-K on May 11, 2017 and incorporated herein by reference.)
4.28	Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated by reference.)
4.29*	Description of Amgen Inc.'s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1+	Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
10.2+	First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.)
10.3+	Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)
10.4+*	Form of Grant of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 10, 2019.)
10.5+*	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 10, 2019.)
10.6+	Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.7+*	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on December 10, 2019.)
10.8+*	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.)
10.9+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.10+*	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.)
10.11+*	

Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.)

10.12+ Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)

10.13+ First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)

10.14+*	Second Amendment to the Amgen Inc. Supplemental Retirement Plan (As Amended and Restated effective October 23, 2019).
10.15+	Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.)
10.16+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.17+	First Amendment to the Amgen Inc. Executive Incentive Plan, effective December 13, 2012. (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.)
10.18+	Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.19+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.20+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.21+*	Second Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2020).
10.22+	Agreement between Amgen Inc. and David W. Meline, effective July 21, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2014 on October 29, 2014 and incorporated herein by reference.)
10.23+	Agreement between Amgen Inc. and Jonathan Graham, dated May 11, 2015. (Filed as an exhibit to Form 10-Q/A for the quarter ended June 30, 2015 on August 6, 2015 and incorporated herein by reference.)
10.24+	Agreement between Amgen Inc. and Murdo Gordon, dated July 25, 2018. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2018 on October 31, 2018 and incorporated herein by reference.)
10.25	Second Amended and Restated Credit Agreement, dated December 12, 2019, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent. (Filed as an exhibit to Form 8-K on December 12, 2019 and incorporated herein by reference.)
10.26	Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)
10.27	Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.28	Letter Agreement, dated June 25, 2019, by and between Amgen Inc. and UCB Celltech (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively

harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2019 on July 31, 2019 and incorporated herein by reference.)

10.29 Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)

10.30 Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)

10.31 Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)

10.32	Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.33	Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.34	Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
10.35	Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.36	Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.37	Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.38	Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.39	Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.40	Amendment No. 1 to the Collaboration Agreement, dated March 20, 2018, by and between Novartis Pharma AG and Amgen Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.)
10.41*	Collaboration Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene Switzerland GmbH, a wholly-owned subsidiary of BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed).
10.42*	Guarantee, dated as of October 31, 2019, made by and among BeiGene, Ltd. and Amgen Inc.
10.43	Share Purchase Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.44	Amendment No. 1 to Share Purchase Agreement, dated December 6, 2019, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
21*	Subsidiaries of the Company.

23	Consent of the Independent Registered Public Accounting Firm. The consent is set forth on page 77 of this Annual Report on the 10-K.
24	Power of Attorney. The Power of Attorney is set forth on page 78 of this Annual Report on Form 10-K.
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.

101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

(* = filed herewith)
(** = furnished herewith and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended)
(+ = management contract or compensatory plan or arrangement)

Item 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMGEN INC.
(Registrant)

Date: February 12, 2020

By: /s/ PETER H. GRIFFITH

Peter H. Griffith
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-3 No. 333-236351) of Amgen Inc.,

- Registration Statement (Form S-8 No. 333-159377) pertaining to the Amgen Inc. 2009 Equity Incentive Plan,

- Registration Statement (Form S-8 No. 33-39183) pertaining to the Amended and Restated Employee Stock Purchase Plan,

- Registration Statements (Form S-8 No. 33-39104, as amended by Form S-8 Nos. 333-144581 and 333-216719) pertaining to the Amended and Restated Amgen Retirement and Savings Plan (formerly known as the Amgen Retirement and Savings Plan),

- Registration Statements (Form S-8 Nos. 33-47605, 333-144580 and 333-216715) pertaining to the Retirement and Savings Plan for Amgen Manufacturing, Limited (formerly known as the Retirement and Savings Plan for Amgen Manufacturing, Inc.),

- Registration Statements (Form S-8 Nos. 333-81284, 333-177868 and 333-216723) pertaining to the Amgen Nonqualified Deferred Compensation Plan, and

- Registration Statement (Form S-8 No. 333-176240) pertaining to the Amgen Profit Sharing Plan for Employees in Ireland;

of our reports dated February 12, 2020, with respect to the consolidated financial statements and schedule of Amgen Inc. and the effectiveness of internal control over financial reporting of Amgen Inc. included in this Annual Report (Form 10-K) of Amgen Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Los Angeles, California
February 12, 2020

EXHIBIT 24

POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Peter H. Griffith, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming that said attorney-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/S/ ROBERT A. BRADWAY **Robert A. Bradway**	Chairman of the Board, Chief Executive Officer and President, and Director (Principal Executive Officer)	2/12/2020
/S/ PETER H. GRIFFITH **Peter H. Griffith**	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	2/12/2020
/S/ WANDA M. AUSTIN **Wanda M. Austin**	Director	2/12/2020
/S/ BRIAN J. DRUKER **Brian J. Druker**	Director	2/12/2020
/S/ ROBERT A. ECKERT **Robert A. Eckert**	Director	2/12/2020
/S/ GREG C. GARLAND **Greg C. Garland**	Director	2/12/2020
/S/ FRED HASSAN **Fred Hassan**	Director	2/12/2020
/S/ REBECCA M. HENDERSON **Rebecca M. Henderson**	Director	2/12/2020
/S/ CHARLES M. HOLLEY, JR. **Charles M. Holley, Jr.**	Director	2/12/2020
/S/ TYLER JACKS **Tyler Jacks**	Director	2/12/2020
/S/ ELLEN J. KULLMAN **Ellen J. Kullman**	Director	2/12/2020
/S/ RONALD D. SUGAR **Ronald D. Sugar**	Director	2/12/2020
/S/ R. SANDERS WILLIAMS **R. Sanders Williams**	Director	2/12/2020

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Amgen Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amgen Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 12, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Sales deductions

Description of the Matter

As of December 31, 2019, the Company recorded accrued sales deductions of $3.9 billion. As described in Note 1 to the financial statements under the caption "Product sales and sales deductions," revenues from product sales are recognized net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions, (collectively sales deductions), which are established at the time of sale.

Auditing the estimation of sales deductions, which are netted against product sales, is complex, requires significant judgment, and the amounts involved are material to the financial statements taken as a whole. Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, and is based on an amount that reflects the consideration to which the Company expects to be entitled, which represents an amount that is net of accruals for estimated sales deductions. The estimated sales deductions are based on current contractual and statutory requirements, market events and trends, internal and external historical data, and forecasted customer buying patterns.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the sales deduction processes. This included testing controls over management's review of significant assumptions and inputs used in the estimate of sales deductions, including actual sales, contractual terms, historical experience, wholesaler inventory levels, demand data and estimated patient population. We also tested management's controls over the accuracy of forecasting demand activity as well as the completeness and accuracy of all other components included in the final sales deduction estimates.

To test management's estimated sales deductions, we obtained management's calculations for the respective estimates and performed the following procedures, among others. We tested management's estimation process over the determination of sales discount accruals by developing an independent expectation of the estimated accrual rate, including a comparison of rates used in management's forecast to rates in the underlying contracts, performing a lookback analysis using actual historical data to evaluate the forecasted amounts, assessing subsequent events to determine whether there was any new information that would require adjustment to the initial accruals, evaluating trends in actual sales and discount accrual balances, comparing cash receipts to product sales, confirming terms and conditions for a sample of contracts with the Company's customers, testing a sample of credits issued and payments made throughout the year, and agreeing rates to underlying contract terms.

Unrecognized Tax Benefits

Description of the Matter

As discussed in Notes 1 and 6 to the consolidated financial statements, the Company operates in various jurisdictions in which differing interpretations of complex tax laws and regulations create uncertainty and necessitate the use of significant judgment in the determination of the Company's unrecognized tax benefits related to allocation of profits among various jurisdictions ("transfer pricing"), particularly in the U.S. federal tax jurisdiction where the Company has significant assets and operations. In this regard, the Company uses significant judgment in (1) determining whether a tax position's technical merits are more-likely-than-not to be sustained and (2) measuring the amount of tax benefit that qualifies for recognition. As of December 31, 2019, the Company accrued $3.3 billion of gross unrecognized tax benefits including transfer pricing. Auditing the assessment of the technical merits and measurement of the Company's unrecognized tax benefits is challenging because they can be complex, highly judgmental, and based on interpretations of tax laws and regulations.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the Company's process to assess the technical merits of its tax positions, as well as management's process to measure the unrecognized tax benefits of those tax positions, particularly in regard to transfer pricing. This included testing controls over management's review of the inputs, calculations, assumptions and methods selected to measure the amount of tax benefits that qualify for recognition.

We involved tax and transfer pricing professionals to assist in assessing the technical merits and measurement of certain of the Company's unrecognized tax benefits. Depending on the nature of the specific tax position and, as applicable, developments with the relevant tax authorities, our procedures included obtaining and reviewing the Company's correspondence with such tax authorities and evaluating certain third-party advice to support the Company's evaluations and recorded positions. We used our knowledge of and experience with how the income tax laws and regulations related to transfer pricing are applied by the relevant tax authorities to evaluate the Company's accounting for its unrecognized tax benefits. We evaluated developments in the applicable regulatory environments to assess potential effects on the Company's recorded positions. We analyzed the assumptions and data used by the Company when it determined the amount of tax benefits to recognize, including applicable interest and penalties, and we tested the accuracy of those underlying calculations. We have also evaluated the Company's income tax disclosures included in Note 6 in relation to these matters.

We have served as the Company's auditor since 1980.
Los Angeles, California
February 12, 2020

AMGEN INC.

CONSOLIDATED STATEMENTS OF INCOME

Years ended December 31, 2019, 2018 and 2017

(In millions, except per-share data)

	2019	2018	2017
Revenues:			
Product sales	$ 22,204	$ 22,533	$ 21,795
Other revenues	1,158	1,214	1,054
Total revenues	23,362	23,747	22,849
Operating expenses:			
Cost of sales	4,356	4,101	4,069
Research and development	4,116	3,737	3,562
Selling, general and administrative	5,150	5,332	4,870
Other	66	314	375
Total operating expenses	13,688	13,484	12,876
Operating income	9,674	10,263	9,973
Interest expense, net	1,289	1,392	1,304
Interest and other income, net	753	674	928
Income before income taxes	9,138	9,545	9,597
Provision for income taxes	1,296	1,151	7,618
Net income	$ 7,842	$ 8,394	$ 1,979
Earnings per share:			
Basic	$ 12.96	$ 12.70	$ 2.71
Diluted	$ 12.88	$ 12.62	$ 2.69
Shares used in the calculation of earnings per share:			
Basic	605	661	731
Diluted	609	665	735

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Years ended December 31, 2019, 2018 and 2017

(In millions)

	2019	2018	2017
Net income	$ 7,842	$ 8,394	$ 1,979
Other comprehensive income (loss), net of reclassification adjustments and taxes:			
(Losses) gains on foreign currency translation	(48)	(141)	81
(Losses) gains on cash flow hedges	(66)	247	(288)
Gains (losses) on available-for-sale securities	360	(185)	(6)
Other (losses) gains	(5)	(2)	5
Other comprehensive income (loss), net of taxes	241	(81)	(208)
Comprehensive income	$ 8,083	$ 8,313	$ 1,771

See accompanying notes.

AMGEN INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2019 and 2018

(In millions, except per-share data)

	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,037	$ 6,945
Marketable securities	2,874	22,359
Trade receivables, net	4,057	3,580
Inventories	3,584	2,940
Other current assets	1,888	1,794
Total current assets	18,440	37,618
Property, plant and equipment, net	4,928	4,958
Intangible assets, net	19,413	7,443
Goodwill	14,703	14,699
Other assets	2,223	1,698
Total assets	$ 59,707	$ 66,416
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,371	$ 1,207
Accrued liabilities	8,511	7,862
Current portion of long-term debt	2,953	4,419
Total current liabilities	12,835	13,488
Long-term debt	26,950	29,510
Long-term deferred tax liabilities	606	864
Long-term tax liabilities	8,037	8,770
Other noncurrent liabilities	1,606	1,284
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value per share; 2,750.0 shares authorized; outstanding—591.4 shares in 2019 and 629.6 shares in 2018	31,531	31,246
Accumulated deficit	(21,330)	(17,977)
Accumulated other comprehensive loss	(528)	(769)
Total stockholders' equity	9,673	12,500
Total liabilities and stockholders' equity	$ 59,707	$ 66,416

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended December 31, 2019, 2018 and 2017

(In millions, except per-share data)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of December 31, 2016	738.2	$ 30,784	$ (438)	$ (471)	$ 29,875
Net income	—	—	1,979	—	1,979
Other comprehensive loss, net of taxes	—	—	—	(208)	(208)
Dividends declared on common stock ($4.77 per share)	—	—	(3,487)	—	(3,487)
Issuance of common stock in connection with the Company's equity award programs	2.5	52	—	—	52
Stock-based compensation expense	—	347	—	—	347
Tax impact related to employee stock-based compensation expense	—	(191)	—	—	(191)
Repurchases of common stock	(18.5)	—	(3,126)	—	(3,126)
Balance as of December 31, 2017	722.2	30,992	(5,072)	(679)	25,241
Cumulative effect of changes in accounting principles, net of taxes	—	—	38	(9)	29
Net income	—	—	8,394	—	8,394
Other comprehensive loss, net of taxes	—	—	—	(81)	(81)
Dividends declared on common stock ($5.41 per share)	—	—	(3,482)	—	(3,482)
Issuance of common stock in connection with the Company's equity award programs	1.9	56	—	—	56
Stock-based compensation expense	—	327	—	—	327
Tax impact related to employee stock-based compensation expense	—	(129)	—	—	(129)
Repurchases of common stock	(94.5)	—	(17,855)	—	(17,855)
Balance as of December 31, 2018	629.6	31,246	(17,977)	(769)	12,500
Net income	—	—	7,842	—	7,842
Other comprehensive income, net of taxes	—	—	—	241	241
Dividends declared on common stock ($5.95 per share)	—	—	(3,555)	—	(3,555)
Issuance of common stock in connection with the Company's equity award programs	2.0	97	—	—	97
Stock-based compensation expense	—	323	—	—	323
Tax impact related to employee stock-based compensation expense	—	(135)	—	—	(135)
Repurchases of common stock	(40.2)	—	(7,640)	—	(7,640)
Balance as of December 31, 2019	591.4	$ 31,531	$ (21,330)	$ (528)	$ 9,673

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2019, 2018 and 2017

(In millions)

	2019	2018	2017
Cash flows from operating activities:			
Net income	$ 7,842	$ 8,394	$ 1,979
Depreciation, amortization and other	2,206	1,946	1,955
Stock-based compensation expense	308	311	329
Deferred income taxes	(289)	(363)	(1,330)
Other items, net	(186)	386	334
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	(504)	(378)	(58)
Inventories	(66)	(3)	133
Other assets	10	35	(24)
Accounts payable	164	(143)	424
Accrued income taxes, net	(585)	(361)	523
Long-term tax liabilities	(146)	258	6,681
Other liabilities	396	1,214	231
Net cash provided by operating activities	9,150	11,296	11,177
Cash flows from investing activities:			
Purchases of marketable securities	(9,394)	(18,741)	(33,607)
Proceeds from sales of marketable securities	8,842	28,356	24,240
Proceeds from maturities of marketable securities	20,548	5,412	6,174
Purchases of property, plant and equipment	(618)	(738)	(664)
Cash paid for acquisitions, net of cash acquired	(13,617)	195	(19)
Other	(52)	(145)	(148)
Net cash provided by (used in) investing activities	5,709	14,339	(4,024)
Cash flows from financing activities:			
Net proceeds from issuance of debt	—	—	4,476
Repayment of debt	(4,514)	(1,121)	(4,405)
Repurchases of common stock	(7,702)	(17,794)	(3,160)
Dividends paid	(3,509)	(3,507)	(3,365)
Withholding taxes arising from shares withheld for share-based payments	(137)	(126)	(191)
Other	95	58	51
Net cash used in financing activities	(15,767)	(22,490)	(6,594)
(Decrease) increase in cash and cash equivalents	(908)	3,145	559
Cash and cash equivalents at beginning of year	6,945	3,800	3,241
Cash and cash equivalents at end of year	$ 6,037	$ 6,945	$ 3,800

See accompanying notes.

1. Summary of significant accounting policies

Business

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. We operate in one business segment: human therapeutics.

Principles of consolidation

The consolidated financial statements include the accounts of Amgen as well as its majority-owned subsidiaries. We do not have any significant interests in any variable interest entities. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Revenues

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that an adjustment is appropriate. Accruals are also adjusted to reflect actual results. Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given period, can be affected by the mix of products sold. Included in sales deductions are immaterial net adjustments related to prior-period sales due to changes in estimates. Historically, such amounts have represented less than 1% of the aggregate sales deductions charged against product sales.

Returns are estimated through comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. Historically, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-period sales return provisions have historically been immaterial.

Our payment terms vary by types and locations of customers and the products or services offered. Payment terms differ by jurisdiction and customer, but payment is generally required in a term ranging from 30 to 120 days from date of shipment or satisfaction of the performance obligation. For certain products or services and certain customer types, we may require payment before products are delivered or services are rendered to customers.

Indirect taxes collected from customers and remitted to government authorities and that are related to sales of the Company's products, primarily in Europe, are excluded from revenues.

As a practical expedient, sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in Selling, general and administrative expense in the Consolidated Statements of Income.

Other revenues

Other revenues consist primarily of royalty income and corporate partner revenues. Royalties from licensees are based on third-party sales of licensed products and are recorded when the related third-party product sale occurs. Royalty estimates are based on historical and forecasted sales trends. Corporate partner revenues are composed mainly of license fees and milestones earned and our share of commercial profits generated from collaborations. See Arrangements with multiple-performance obligations, discussed below.

Arrangements with multiple-performance obligations

From time to time, we enter into arrangements for the research and development (R&D), manufacture and/or commercialization of products and product candidates. Such arrangements may require us to deliver various rights, services and/or goods, including intellectual property rights/licenses, R&D services, manufacturing services and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to Amgen in the form of nonrefundable, upfront license fees; development and commercial performance milestone payments; royalty payments; and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or by using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods or services is transferred. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. We utilize the sales- and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

Research and development costs

R&D costs are expensed as incurred and include primarily salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems' costs; and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs and cost recoveries associated with third-party R&D arrangements, including upfront fees and milestones paid to third parties in connection with technologies that had not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 8, Collaborations and Note 21, Subsequent events.

Selling, general and administrative costs

Selling, general and administrative (SG&A) costs are composed primarily of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses; the U.S. healthcare reform federal excise fee on Branded Prescription Pharmaceutical Manufacturers and Importers; and other general and administrative costs. Advertising costs are expensed as incurred and were $789 million, $674 million and $620 million during the years ended December 31, 2019, 2018 and 2017, respectively. SG&A expenses also include costs and cost recoveries associated with marketing and promotion efforts under certain collaborative arrangements. Net payment or reimbursement of SG&A costs is recognized when the obligations are incurred or we become entitled to the cost recovery. See Note 8, Collaborations.

Leases

Adoption of new lease standard

In February 2016, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the accounting and disclosure of leases. This new standard requires that lessees recognize the assets and liabilities that arise from leases on the balance sheet, including leases classified as operating leases, and that they disclose qualitative and quantitative information about leasing arrangements. The FASB subsequently

issued additional amendments to address issues arising from the implementation of the new lease standard. We adopted this standard as of January 1, 2019, using the modified-retrospective method, which provides a method for recording existing leases at adoption. We used the adoption date as our date of initial application, and thus, comparative-period financial information is not presented for periods prior to the adoption date.

In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed us to carry forward the historical lease classification.

Adoption of the new standard resulted in total lease liabilities of $510 million and right-of-use (ROU) assets of $439 million as of January 1, 2019. The difference between the initial lease liabilities and the ROU assets is related primarily to previously existing lease liabilities. The standard did not materially impact our Consolidated Statements of Income and had no impact on our Consolidated Statements of Cash Flows. Our accounting policies under the new standard are described below. See Note 13, Leases.

Lease recognition

At inception of a contract, we determine whether an arrangement is or contains a lease. For all leases, we determine the classification as either operating or financing. Operating leases are included in Other assets, Accrued liabilities and Other noncurrent liabilities in our Consolidated Balance Sheets.

ROU assets represent our right to use an underlying asset for the lease term, and lease liabilities represent our obligation to make lease payments under the lease. Lease recognition occurs at the commencement date, and lease liability amounts are based on the present value of lease payments made during the lease term. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Because most of our leases do not provide information to determine an implicit interest rate, we use our incremental borrowing rate in determining the present value of lease payments. ROU assets also include any lease payments made prior to the commencement date and exclude lease incentives received. Operating lease expense is recognized on a straight-line basis over the lease term.

We have lease agreements with both lease and nonlease components, which are generally accounted for together as a single lease component. In addition, for certain vehicle and equipment leases, we apply a portfolio approach to determine the lease term and discount rate.

Stock-based compensation

We have stock-based compensation plans under which various types of equity-based awards are granted, including restricted stock units (RSUs), performance units and stock options. The fair values of RSUs and stock option awards, which are subject only to service conditions with graded vesting, are recognized as compensation expense, generally on a straight-line basis over the service period, net of estimated forfeitures. The fair values of performance unit awards are recognized as compensation expense, generally on a straight-line basis from the grant date to the end of the performance period. See Note 4, Stock-based compensation.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate. Significant judgment is required in determining our provision for income taxes and income tax assets and liabilities, including evaluating uncertainties in the application of accounting principles and complex tax laws. Deferred income taxes are recorded for the expected tax consequences of temporary differences between the bases of assets and liabilities, as well as for loss and tax credit carryforwards for financial reporting purposes and amounts recognized for income tax purposes. We record a valuation allowance to reduce our deferred tax assets to the amount of future tax benefit that is more likely than not to be realized.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by tax authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits (UTBs) is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by tax authorities, new information obtained during a tax examination or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense. See Note 6, Income taxes.

Acquisitions

We first determine whether a set of assets acquired constitute a business and should be accounted for as a business combination. If the assets acquired are not a business, we account for the transaction as an asset acquisition. Business combinations are accounted for by using the acquisition method of accounting. Under the acquisition method, assets acquired, including in-process research and development (IPR&D) projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The

excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with a business combination (including the assumption of an acquiree's liability arising from an acquisition it consummated prior to our acquisition) are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in earnings. In contrast, asset acquisitions are accounted for using a cost accumulation and allocation model. Under this model, the cost of the acquisition is allocated to the assets acquired

and liabilities assumed. Contingent consideration obligations incurred in connection with an asset acquisition are recorded when it is probable that they will occur and they can be reasonably estimated. See Note 2, Acquisitions, and Note 17, Fair value measurement.

Cash equivalents

We consider cash equivalents to be only those investments that are highly liquid, readily convertible to cash and which mature within three months from the date of purchase.

Interest-bearing securities

We consider our interest-bearing securities investment portfolio available-for-sale, and accordingly, these investments are recorded at fair value, with unrealized gains and losses recorded in Accumulated other comprehensive income (loss) (AOCI). Investments with maturities beyond one year may be classified as short-term marketable securities in the Consolidated Balance Sheets due to their highly liquid nature and because they represent the Company's investments that are available for current operations. See Note 9, Investments, and Note 17, Fair value measurement.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner that approximates the first-in, first-out method. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. See Note 10, Inventories.

Derivatives

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Consolidated Balance Sheets. The accounting for changes in the fair value of a derivative instrument depends on whether the derivative has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of hedging relationship. For derivatives formally designated as hedges, we assess both at inception and quarterly thereafter whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item. Our derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings. See Note 17, Fair value measurement, and Note 18, Derivative instruments.

Property, plant and equipment, net

Property, plant and equipment is recorded at historical cost, net of accumulated depreciation, amortization and, if applicable, impairment charges. We review our property, plant and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Depreciation is provided over the assets' useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms. See Note 11, Property, plant and equipment.

Goodwill and other intangible assets

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is provided over their estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note 12, Goodwill and other intangible assets.

The fair values of IPR&D projects acquired in a business combination that are not complete are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related R&D efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market the resulting products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods.

Capitalized IPR&D projects are tested for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. We consider various factors for potential

impairment, including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays in obtaining marketing approval, the inability to bring a product to market and the introduction or advancement of competitors' products could result in partial or full impairment of the related intangible assets.

We perform an impairment test of goodwill annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. To date, an impairment of goodwill has not been recorded. See Note 12, Goodwill and other intangible assets.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. Certain of these proceedings are discussed in Note 19, Contingencies and commitments. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Foreign currency translation

The net assets of international subsidiaries whose local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating net assets of these subsidiaries at changing rates are recognized in AOCI. The subsidiaries' earnings are translated into U.S. dollars using average exchange rates.

Other recent accounting pronouncements

In June 2016, the FASB issued a new accounting standard that amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the incurred-loss model with an expected-loss model. Accordingly, these financial assets will be presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The new standard is effective for interim and annual periods beginning on January 1, 2020. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. We have substantially completed our impact assessment and do not currently anticipate a material impact on our consolidated financial statements.

2. Acquisitions

Otezla® (apremilast)

On November 21, 2019, we acquired worldwide rights to Otezla®, the only oral, non-biologic treatment for psoriasis and psoriatic arthritis, along with certain related assets and liabilities, from Celgene Corporation (Celgene). Otezla® is used primarily for the treatment of patients with moderate-to-severe plaque psoriasis for whom phototherapy or systemic therapy is appropriate and is approved in more than 50 markets outside the United States, including the European Union and Japan. The acquisition was accounted for as an asset acquisition under GAAP because substantially all the value of the assets acquired was concentrated in the global intellectual property rights of Otezla®. Otezla®'s operations have been included in our consolidated financial statements commencing on the acquisition date.

The following table summarizes the consideration transferred and the allocation of the estimated accumulated cost, including tax adjustments, to the assets acquired and liabilities assumed (in millions):

	Amounts
Cash purchase price	$ 13,400
Transaction costs	40
Accumulated cost (consideration transferred)	$ 13,440
Intangible assets:	
Developed-product-technology rights	$ 13,007
Marketing-related rights	195
Inventory	367
Deferred tax liability, net	(24)
Deferred credit	(96)
Other liabilities, net	(9)
Total assets acquired, net	$ 13,440

Amgen allocated the accumulated cost of the acquisition to the assets acquired based on their relative fair values. The accumulated cost of the acquisition includes direct acquisition-related costs and applicable taxes. Goodwill is not recognized in the accounting for an asset acquisition. Rather, the excess of the accumulated cost over the fair value of the net assets acquired is reallocated to the nonfinancial assets acquired.

The developed-product-technology rights acquired relate to Otezla®. The estimated fair value was determined by using a multi-period excess earnings income approach, which is based on the present value of the incremental after-tax cash flows attributable only to the intangible asset. The developed-product-technology rights will be amortized over a weighted-average period of 8.5 years by using the straight-line method.

The estimated fair value of marketing-related rights, which relate to assembled workforce, was determined using a replacement cost approach, which consists of developing an estimate of the current cost of a similar new asset having the nearest equivalent utility to the asset being valued. The assembled workforce will be amortized over a period of 5 years by using the straight-line method.

The estimated fair value of the acquired inventory was determined using the comparative sales method, which uses actual or expected selling prices of inventory as the base amount to which adjustments for selling effort and a profit on the buyer's effort are applied. Inventory fair value adjustments will be amortized as inventory turns over, which we estimate to approximate 2.5 years.

Nuevolution AB

On July 15, 2019, we acquired all of the outstanding stock of Nuevolution AB (Nuevolution), a publicly traded, Denmark-based biotechnology company with a leading small molecule drug discovery platform, for total consideration of $183 million in cash. The transaction, which was accounted for as a business combination, expands our ability to discover novel small molecules against difficult-to-drug targets and with greater speed and efficiency. Nuevolution's operations, which are not material, have been included in our consolidated financial statements commencing on the acquisition date.

We allocated the consideration to acquire Nuevolution to finite-lived intangible assets of $150 million, comprised primarily of technology rights for a drug discovery platform with an estimated useful life of 10 years; goodwill of $26 million, which is not tax deductible; deferred tax liabilities of $22 million; and other net assets of $29 million.

The estimated fair values of intangible assets were determined primarily by using a probability-weighted-income approach, which discounts expected future cash flows to present value by using a discount rate that represents the estimated rate that market participants would use to value the intangible assets.

Our accounting for this acquisition is preliminary and will be finalized upon completion of our analysis to determine the acquisition date fair values of certain assets acquired, tax-related items and the residual impact on goodwill.

Kirin-Amgen, Inc.

During the first quarter of 2018, we acquired the remaining 50% ownership of Kirin-Amgen, Inc. (K-A), from Kirin Holdings Company, Limited (Kirin), making K-A a wholly owned subsidiary of Amgen. Upon its acquisition, K-A's operations have been included in our consolidated financial statements commencing on the share acquisition date. The acquisition relieved Amgen of future royalty obligations to K-A.

Prior to the share acquisition date, we owned 50% of K-A and accounted for our interest in K-A by using the equity method of accounting.

The transaction was accounted for as a step acquisition of a business in which we were required to remeasure our existing 50% ownership interest at fair value. In addition, we were required to effectively settle our preexisting relationship with K-A, which resulted in a loss. Together the gain on the remeasurement of our existing ownership interest and the loss from the settlement of the preexisting relationship resulted in a net gain of $80 million, which was recorded in Interest and other income, net, in the Consolidated Statements of Income.

The primary means of consideration for this transaction was a payment of $780 million in cash. The aggregate share acquisition date consideration to acquire the remaining 50% ownership in K-A and the fair value of Amgen's preacquisition investment consisted of the following (in millions):

	Amounts
Total cash paid to Kirin	$ 780
Fair value of contingent consideration obligation	45
Loss on settlement of preexisting relationship	(168)
Total consideration transferred to acquire K-A	657
Fair value of Amgen's investment in K-A	825
Total acquisition date fair value	$ 1,482

In connection with this acquisition, we are obligated to make single-digit royalty payments to Kirin contingent upon sales of brodalumab. The estimated fair value of this contingent consideration obligation was $45 million as of the share acquisition date.

The fair values of assets acquired and liabilities assumed consisted of cash of $977 million, licensing rights of $470 million, deferred tax liabilities of $102 million, other assets and liabilities of $131 million and goodwill of $6 million. The estimated fair value of acquired licensing rights was determined by using a probability-related-income approach, which is based on the present value of the incremental after-tax cash flows attributable only to the intangible asset. The projected cash flows were based on certain assumptions, including estimates of future revenues and expenses and the time and resources needed to maintain the assets through commercialization. The licensing rights will be amortized over a weighted-average period of four years by using the straight-line method. The excess of the share acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $6 million was recorded as goodwill, which is not deductible for tax purposes. The $131 million in other assets and liabilities represents primarily receivables for royalties earned by K-A but not yet received, offset partially by payables representing R&D expenses incurred but not yet reimbursed by K-A.

Pro forma results of operations for this acquisition have not been presented because this acquisition was not material to our consolidated results of operations.

3. Revenues

We operate in one business segment: human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Revenues by product and by geographic area, based on customers' locations, are presented below. Rest-of-world (ROW) revenues relate to products that are sold primarily in Europe.

Revenues were as follows (in millions):

	Year ended December 31, 2019		
	U.S.	ROW	Total
Enbrel® (etanercept)	$ 5,050	$ 176	$ 5,226
Neulasta® (pegfilgrastim)	2,814	407	3,221
Prolia® (denosumab)	1,772	900	2,672
XGEVA® (denosumab)	1,457	478	1,935
Aranesp® (darbepoetin alfa)	758	971	1,729
KYPROLIS® (carfilzomib)	654	390	1,044
EPOGEN® (epoetin alfa)	867	—	867
Sensipar®/Mimpara® (cinacalcet)	252	299	551
Other products	2,907	2,052	4,959
Total product sales(1)	16,531	5,673	22,204
Other revenues	693	465	1,158
Total revenues	$ 17,224	$ 6,138	$ 23,362

	Year ended December 31, 2018		
	U.S.	ROW	Total
ENBREL	$ 4,807	$ 207	$ 5,014
Neulasta®	3,866	609	4,475
Prolia®	1,500	791	2,291
Aranesp®	942	935	1,877
XGEVA®	1,338	448	1,786
Sensipar®/Mimpara®	1,436	338	1,774
EPOGEN®	1,010	—	1,010
KYPROLIS®	583	385	968
Other products	1,947	1,391	3,338
Total product sales(1)	17,429	5,104	22,533
Other revenues	929	285	1,214
Total revenues	$ 18,358	$ 5,389	$ 23,747

	Year ended December 31, 2017		
	U.S.	ROW	Total
ENBREL	$ 5,206	$ 227	$ 5,433
Neulasta®	3,931	603	4,534
Aranesp®	1,114	939	2,053
Prolia®	1,272	696	1,968
Sensipar®/Mimpara®	1,374	344	1,718
XGEVA®	1,157	418	1,575
EPOGEN®	1,096	—	1,096
KYPROLIS®	562	273	835
Other products	1,419	1,164	2,583
Total product sales[1]	17,131	4,664	21,795
Other revenues	898	156	1,054
Total revenues	$ 18,029	$ 4,820	$ 22,849

[1] Hedging gains and losses, which are included in product sales, were not material for the years ended December 31, 2019, 2018 and 2017.

In the United States, we sell primarily to pharmaceutical wholesale distributors that we utilize as the principal means of distributing our products to healthcare providers. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

We had product sales to three customers, each of them accounting for more than 10% of total revenues for each of the years ended December 31, 2019, 2018 and 2017. For the year ended December 31, 2019, on a combined basis, these customers accounted for 81% of total gross revenues as shown in the following table. Certain information with respect to these customers was as follows (dollar amounts in millions):

	Years ended December 31,		
	2019	2018	2017
AmerisourceBergen Corporation:			
Gross product sales	$ 12,301	$ 12,091	$ 10,742
% of total gross revenues	33 %	33 %	31 %
McKesson Corporation:			
Gross product sales	$ 11,795	$ 11,434	10,625
% of total gross revenues	31 %	31 %	30 %
Cardinal Health, Inc.:			
Gross product sales	$ 6,538	$ 7,475	$ 7,049
% of total gross revenues	17 %	20 %	20 %

As of December 31, 2019 and 2018, amounts due from these three customers each exceeded 10% of gross trade receivables and accounted for 73% and 76%, respectively, of net trade receivables on a combined basis. As of December 31, 2019 and 2018, 27% and 23%, respectively, of trade receivables, net, were due from customers located outside the United States, the majority of which were from Europe. Our total allowance for doubtful accounts as of December 31, 2019 and 2018 was not material.

4. Stock-based compensation

Our Amended and Restated 2009 Equity Incentive Plan (the Amended 2009 Plan) authorizes for issuance to employees of Amgen, employees of Amgen subsidiaries and nonemployee members of our Board of Directors shares of our common stock pursuant to grants of equity-based awards, including RSUs, stock options and performance units. The pool of shares available under the Amended 2009 Plan is reduced by one share for each stock option granted and by 1.9 shares for other types of awards granted, including RSUs and performance units (full-value awards). In general, if any shares subject to an award granted under the Amended 2009 Plan expire or become forfeited, terminated or canceled without the issuance of shares, the shares subject to such awards are added back into the authorized pool on the same basis that they were removed. In addition, under the Amended 2009 Plan, shares withheld to pay for minimum statutory tax obligations with respect to full-value awards are added back into the authorized pool on the basis of 1.9 shares. As of December 31, 2019, the Amended 2009 Plan provides for future grants and/or issuances of up to 28 million shares of our common stock. Stock-based awards under our employee compensation plans are made with newly issued shares reserved for this purpose.

The following table reflects the components of stock-based compensation expense recognized in our Consolidated Statements of Income (in millions):

	Years ended December 31,		
	2019	2018	2017
RSUs	$ 168	$ 165	$ 174
Performance units	105	117	133
Stock options	35	29	22
Total stock-based compensation expense, pretax	308	311	329
Tax benefit from stock-based compensation expense	(67)	(67)	(118)
Total stock-based compensation expense, net of tax	$ 241	$ 244	$ 211

Restricted stock units and stock options

Eligible employees generally receive an annual grant of RSUs and, for certain executive-level employees, stock options, with the size and type of award generally determined by the employee's salary grade and performance level. Certain management and professional-level employees typically receive RSU grants upon commencement of employment. Nonemployee members of our Board of Directors also receive an annual grant of RSUs.

Our RSU and stock option grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including upon death, disability, termination in connection with a change in control and the retirement of employees who meet certain service and/or age requirements. RSUs and stock options generally vest in equal amounts on the second, third and fourth anniversaries of the grant date. RSUs accrue dividend equivalents, which are typically payable in shares, only when and to the extent the underlying RSUs vest and are issued to the recipient.

Restricted stock units

The grant date fair value of an RSU equals the closing price of our common stock on the grant date, as RSUs accrue dividend equivalents during their vesting period. The weighted-average grant date fair values of RSUs granted during the years ended December 31, 2019, 2018 and 2017, were $182.12, $179.18 and $163.99, respectively.

The following table summarizes information regarding our RSUs:

	Year ended December 31, 2019	
	Units (in millions)	Weighted-average grant date fair value
Balance nonvested as of December 31, 2018	3.1	$ 168.11
Granted	1.2	$ 182.12
Vested	(1.0)	$ 163.21
Forfeited	(0.2)	$ 170.52

Balance nonvested as of December 31, 2019	3.1	$	174.97

The total grant date fair values of RSUs that vested during the years ended December 31, 2019, 2018 and 2017, were $160 million, $167 million and $182 million, respectively.

Stock options

The exercise price of stock options is set as the closing price of our common stock on the grant date, and the related number of shares granted is fixed at that point in time. Awards expire 10 years from the date of grant. We use the Black–Scholes option valuation model to estimate the grant date fair value of stock options.

The weighted-average assumptions used in the option valuation model and the resulting weighted-average grant date fair values of stock options granted were as follows:

	Years ended December 31,		
	2019	2018	2017
Closing price of our common stock on grant date	$ 177.31	$ 177.46	$ 162.60
Expected volatility (average of implied and historical volatility)	23.5 %	24.6 %	22.7 %
Expected life (in years)	5.8	5.8	5.8
Risk-free interest rate	2.4 %	2.8 %	2.1 %
Expected dividend yield	3.1 %	2.9 %	2.8 %
Fair value of stock options granted	$ 30.47	$ 34.60	$ 27.54

The following table summarizes information regarding our stock options:

	Year ended December 31, 2019			
	Options (in millions)	Weighted-average exercise price	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in millions)
Balance unexercised as of December 31, 2018	4.4	$ 143.57		
Granted	1.4	$ 177.31		
Exercised	(0.7)	$ 107.13		
Expired/forfeited	(0.3)	$ 171.01		
Balance unexercised as of December 31, 2019	4.8	$ 157.00	7.2	$ 406
Vested or expected to vest as of December 31, 2019	4.6	$ 156.02	7.1	$ 390
Exercisable as of December 31, 2019	1.3	$ 117.13	4.3	$ 162

The total intrinsic values of options exercised during the years ended December 31, 2019, 2018 and 2017, were $68 million, $53 million and $60 million, respectively. The actual tax benefits realized from tax deductions from option exercises during the years ended December 31, 2019, 2018 and 2017, were $15 million, $12 million and $21 million, respectively.

As of December 31, 2019, $308 million of unrecognized compensation cost was related to nonvested restricted stock units and unvested stock options, which is expected to be recognized over a weighted-average period of 1.8 years.

Performance units

Certain management-level employees also receive annual grants of performance units, which give the recipient the right to receive common stock that is contingent upon achievement of specified preestablished goals over the performance period, which is generally three years. The performance goals for the units granted during the years ended December 31, 2019, 2018 and 2017, which are accounted for as equity awards, are based on (i) Amgen's stockholder return compared with a comparator group of companies, which are considered market conditions and are therefore reflected in the grant date fair values of the units, and (ii) Amgen's stand-alone financial performance measures, which are considered performance conditions. The expense recognized for awards is based on the grant

date fair value of a unit multiplied by the number of units expected to be earned with respect to the related performance conditions, net of estimated forfeitures. Depending on the outcome of these performance goals, a recipient may ultimately earn a number of units greater or less than the number of units granted. Shares of our common stock are issued on a one-for-one basis for each performance unit earned. In general, performance unit awards vest at the end of the performance period. The performance award program provides for accelerated or continued vesting in certain circumstances as defined in the plan, including upon death, disability, a change in control and retirement of employees who meet certain service and/or age

requirements. Performance units accrue dividend equivalents that are typically payable in shares only when and to the extent the underlying performance units vest and are issued to the recipient, including with respect to market and performance conditions that affect the number of performance units earned.

We use a payout simulation model to estimate the grant date fair value of performance units. The weighted-average assumptions used in the payout simulation model and the resulting weighted-average grant date fair values of performance units granted were as follows:

	Years ended December 31,		
	2019	2018	2017
Closing price of our common stock on grant date	$ 177.31	$ 177.93	$ 162.60
Volatility	22.1 %	23.8 %	25.9 %
Risk-free interest rate	2.3 %	2.6 %	1.4 %
Fair value of units granted	$ 188.40	$ 189.21	$ 178.87

The payout simulation model assumes correlations of returns of the stock prices of our common stock and the common stocks of the comparator groups of companies and stock price volatilities of the comparator groups of companies to simulate stockholder returns over the performance periods and their resulting impact on the payout percentages based on the contractual terms of the performance units.

As of December 31, 2019 and 2018, 2.0 million and 2.0 million performance units were outstanding with weighted-average grant date fair values of $185.64 and $180.12 per unit, respectively. During the year ended December 31, 2019, 0.8 million performance units with a weighted-average grant date fair value of $188.40 were granted, and 0.2 million performance units with a weighted-average grant date fair value of $186.66 were forfeited.

The total fair values of performance units paid during the years ended December 31, 2019, 2018 and 2017 were $176 million, $133 million and $219 million, respectively, based on the number of performance units earned multiplied by the closing stock price of our common stock on the last day of the performance period.

As of December 31, 2019, $113 million of unrecognized compensation cost was related to nonvested performance units, which is expected to be recognized over a weighted-average period of one year.

5. Defined contribution plan

The Company has defined contribution plans to which certain employees of the Company and participating subsidiaries may defer compensation for income tax purposes. Participants are eligible to receive matching contributions based on their contributions, in addition to other Company contributions. Defined contribution plan expenses were $220 million, $173 million and $196 million for the years ended December 31, 2019, 2018 and 2017, respectively.

6. Income taxes

Income before income taxes included the following (in millions):

	Years ended December 31,		
	2019	2018	2017
Domestic	$ 4,371	$ 4,856	$ 4,436
Foreign	4,767	4,689	5,161
Total income before income taxes	$ 9,138	$ 9,545	$ 9,597

The provision for income taxes included the following (in millions):

	Years ended December 31,		
	2019	2018	2017
Current provision:			
Federal	$ 1,284	$ 1,270	$ 8,615
State	39	17	5
Foreign	277	227	275
Total current provision	1,600	1,514	8,895
Deferred (benefit) provision:			
Federal	(276)	(317)	(1,120)
State	(22)	(7)	—
Foreign	(6)	(39)	(157)
Total deferred (benefit) provision	(304)	(363)	(1,277)
Total provision for income taxes	$ 1,296	$ 1,151	$ 7,618

Deferred income taxes reflect the tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards and the tax effects of net operating loss (NOL) carryforwards. Significant components of our deferred tax assets and liabilities were as follows (in millions):

	December 31,	
	2019	2018
Deferred income tax assets:		
NOL and credit carryforwards	$ 800	$ 810
Accrued expenses	457	428
Expenses capitalized for tax	170	185
Stock-based compensation	91	95
Other	269	174
Total deferred income tax assets	1,787	1,692
Valuation allowance	(517)	(509)
Net deferred income tax assets	1,270	1,183
Deferred income tax liabilities:		
Acquired intangible assets	(1,288)	(1,509)
Debt	(210)	(184)
Other	(286)	(267)
Total deferred income tax liabilities	(1,784)	(1,960)
Total deferred income taxes, net	$ (514)	$ (777)

Valuation allowances are provided to reduce the amounts of our deferred tax assets to an amount that is more likely than not to be realized based on an assessment of positive and negative evidence, including estimates of future taxable income necessary to realize future deductible amounts.

The valuation allowance increased in 2019 due primarily to the Company's expectation that some state R&D credits will not be utilized.

As of December 31, 2019, we had $20 million of federal tax credit carryforwards available to reduce future federal income taxes and have provided no valuation allowance for those federal tax credit carryforwards. The federal tax credit carryforwards expire between 2023 and 2035. We had $605 million of state tax credit carryforwards

available to reduce future state income taxes and have provided a valuation allowance for $482 million of those state tax credit carryforwards. A portion of the state credits for which no valuation allowance has been provided will expire between 2022 and 2034.

As of December 31, 2019, we had $144 million of federal NOL carryforwards available to reduce future federal income taxes and have provided a valuation allowance for $6 million of those federal NOL carryforwards. The federal NOL carryforwards, for which no valuation allowance has been provided, expire between 2020 and 2035. We had $196 million of state NOL carryforwards available to reduce future state income taxes and have provided a valuation allowance for $196 million of those state NOL carryforwards. We had $2.0 billion of foreign NOL carryforwards available to reduce future foreign income taxes and have provided a valuation allowance for $516 million of those foreign NOL carryforwards. For the foreign NOLs with no valuation allowance provided, $822 million has no expiry; and the remainder will expire between 2020 and 2024.

The reconciliations of the total gross amounts of UTBs were as follows (in millions):

	Years ended December 31,		
	2019	2018	2017
Beginning balance	$ 3,061	$ 2,953	$ 2,543
Additions based on tax positions related to the current year	215	173	447
Additions based on tax positions related to prior years	22	13	1
Reductions for tax positions of prior years	(11)	(17)	(5)
Reductions for expiration of statute of limitations	—	—	(5)
Settlements	—	(61)	(28)
Ending balance	$ 3,287	$ 3,061	$ 2,953

Substantially all of the UTBs as of December 31, 2019, if recognized, would affect our effective tax rate.

Interest and penalties related to UTBs are included in our provision for income taxes. During the years ended December 31, 2019, 2018 and 2017, we recognized $198 million, $137 million and $56 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. As of December 31, 2019 and 2018, accrued interest and penalties associated with UTBs were $667 million and $469 million, respectively.

The reconciliations between the federal statutory tax rate applied to income before income taxes and our effective tax rate were as follows:

	Years ended December 31,		
	2019	2018	2017
Federal statutory tax rate	21.0 %	21.0 %	35.0 %
2017 Tax Act, net repatriation tax	— %	— %	70.7 %
Foreign earnings	(4.5 %)	(4.3 %)	(15.8 %)
2017 Tax Act, net deferred tax remeasurement	— %	— %	(6.9 %)
Credits, Puerto Rico Excise Tax	(2.6 %)	(2.5 %)	(2.2 %)
2017 Tax Act, net impact on intercompany sales	— %	(1.8 %)	— %
Interest on uncertain tax positions	1.6 %	1.2 %	0.6 %
Credits, primarily federal R&D	(1.0 %)	(0.8 %)	(0.6 %)
Share-based payments	(0.3 %)	(0.2 %)	(0.7 %)
Other, net	— %	(0.5 %)	(0.7 %)
Effective tax rate	14.2 %	12.1 %	79.4 %

The effective tax rates for the years ended December 31, 2019 and 2018 differ from the federal statutory rate due primarily to impacts of the jurisdictional mix of income and expenses. The effective tax rate for 2017 differs from the federal statutory rate primarily as a result of the Tax Cuts and Jobs Act (the 2017 Tax Act). Primarily all of the benefit to our effective tax rate from foreign earnings results from the Company's operations conducted in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes and are subject to tax incentive grants through 2035. Additionally, the Company's operations conducted in Singapore is subject to a tax incentive grant through 2034. These earnings are also subject to U.S. tax at a reduced rate of 10.5%.

The U.S. territory of Puerto Rico imposes an excise tax on the gross intercompany purchase price of goods and services from our manufacturer in Puerto Rico. The rate of 4% is effective through December 31, 2027. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in cost of sales when the related products are sold. For U.S. income tax purposes, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes when the excise tax is incurred.

Income taxes paid during the years ended December 31, 2019, 2018 and 2017, were $1.9 billion, $1.9 billion and $1.5 billion, respectively.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes may arise with tax authorities involving issues regarding the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and relevant facts. As previously disclosed, we received a Revenue Agent Report (RAR) from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Final resolution of this complex matter is not likely within the next 12 months and could have a material impact on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments substantially greater or less than amounts accrued. We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009. In addition, we are currently under examination by a number of state and foreign tax jurisdictions.

7. Earnings per share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which include primarily shares that may be issued under our stock option, restricted stock and performance unit award programs (collectively, dilutive securities), as determined by using the treasury stock method.

The computations for basic and diluted EPS were as follows (in millions, except per-share data):

	Years ended December 31,		
	2019	2018	2017
Income (Numerator):			
Net income for basic and diluted EPS	$ 7,842	$ 8,394	$ 1,979
Shares (Denominator):			
Weighted-average shares for basic EPS	605	661	731
Effect of dilutive securities	4	4	4
Weighted-average shares for diluted EPS	609	665	735
Basic EPS	$ 12.96	$ 12.70	$ 2.71
Diluted EPS	$ 12.88	$ 12.62	$ 2.69

For each of the three years ended December 31, 2019, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

8. Collaborations

A collaborative arrangement is a contractual arrangement that involves a joint operating activity. Such arrangements involve two or more parties that are both (i) active participants in the activity and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for nonrefundable upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration arrangements are performed with no guarantee of either technological or commercial success, and each arrangement is unique in nature. See Note 1, Summary of significant accounting policies, for additional discussion of revenues recognized for these types of arrangements. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line items in the Consolidated Statements of Income, net of any payments due to or reimbursements due from our collaboration partners, with such reimbursements being recognized at the time the party becomes obligated to pay. Our significant arrangements are discussed below.

Novartis AG

We are in a collaboration with Novartis AG (Novartis) to jointly develop and commercialize Aimovig® (erenumab-aooe). In the United States, Amgen and Novartis jointly develop and collaborate on the commercialization of Aimovig®. Amgen, as the principal, recognizes product sales of Aimovig® in the United States, shares U.S. commercialization costs with Novartis and pays Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig® and other specified migraine programs. Novartis pays Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories and funds a portion of global R&D expenses. In addition, Novartis will make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds are achieved with respect to Aimovig® in the United States. Amgen manufactures and supplies Aimovig® worldwide. The migraine collaboration will continue for the commercial lives of the products unless terminated in accordance with its terms.

We are currently involved in litigation with Novartis over our collaboration agreements for the development and commercialization of Aimovig®. See Note 19, Contingencies and commitments.

During the year ended December 31, 2019, net costs recovered from Novartis for migraine products were $187 million and were recorded primarily in Selling, general and administrative expense in the Consolidated Statements of Income. During the year ended December 31, 2018, net costs paid to Novartis for migraine products were $44 million and were recorded primarily in Selling, general and administrative expense in the Consolidated Statements of Income. During the year ended December 31, 2017, net costs recovered from Novartis for migraine products were $124 million and were recorded primarily in R&D expense in the Consolidated Statements of Income. During the years ended December 31, 2019 and 2018, royalties due to Novartis for the migraine products were $115 million and $43 million, respectively, and were recorded in Cost of sales in the Consolidated Statements of Income. During the years ended December 31, 2019 and 2018, royalties due from Novartis for the migraine products were not material. As a result of certain regulatory and commercial events, we received milestone payments from Novartis of $295 million during the year ended December 31, 2018, which was recorded in Other revenues in the Consolidated Statements of Income.

Bayer HealthCare LLC

We are in a collaboration with Bayer HealthCare LLC (Bayer) to jointly develop and commercialize Nexavar® (sorafenib) worldwide, except in Japan. The rights to develop and market Nexavar® in Japan are reserved to Bayer. Nexavar® is currently marketed and sold in more than 100 countries around the world for the treatment of unresectable liver cancer and advanced kidney cancer. In the United States, Nexavar® is also approved for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

In 2015, we amended the terms of our collaboration agreement with Bayer, which terminated the co-promotion agreement in the United States and transferred all U.S. operational responsibilities to Bayer, including commercial and medical affairs activities. Prior to the termination of the co-promotion agreement, we co-promoted Nexavar® with Bayer and shared equally in the profits or losses in the United States. In lieu of this profit share, Bayer now pays Amgen a royalty on U.S. sales of Nexavar® at a percentage rate in the high 30s. Amgen no longer contributes sales

force personnel or medical liaisons to support Nexavar® in the United States. There are no changes to the global R&D or non-U.S. profit share arrangements in the original agreement, as discussed below.

In all countries outside the United States and Japan, Bayer manages all commercialization activities and incurs all of the sales and marketing expenditures and mutually agreed R&D expenses, for which we continue to reimburse Bayer for half. In these countries, we continue to receive 50% of net profits on sales of Nexavar® after deducting certain Bayer-related costs.

The agreement with Bayer will terminate at the later of the date when patents expire that were issued in connection with product candidates discovered under the agreement or on the last day that we or Bayer market or sell products commercialized under the agreement anywhere in the world. Patents related to Nexavar® begin to expire in 2020.

During the years ended December 31, 2019, 2018 and 2017, Amgen recorded Nexavar® net profits of $210 million, $164 million and $161 million, respectively, which were recognized as Other revenues in the Consolidated Statements of Income. During the years ended December 31, 2019, 2018 and 2017, Amgen recorded royalty income of $79 million, $91 million and $133 million, respectively, in Other revenues in the Consolidated Statements of Income, pursuant to the 2015 amendment to the collaboration agreement. Net R&D expenses related to the agreement were not material for the years ended December 31, 2019, 2018 and 2017.

Other

In addition to the collaborations discussed above, we have various other collaborations that are not individually significant to our business at this time. Pursuant to the terms of those agreements, we may be required to pay additional amounts or we may receive additional amounts upon the achievement of various development and commercial milestones, which in the aggregate could be significant. We may also incur or have reimbursed to us significant R&D costs if the related product candidate were to advance to late-stage clinical trials. In addition, if any products related to these collaborations are approved for sale, we may be required to pay significant royalties or we may receive significant royalties on future sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurrence.

9. Investments

Available-for-sale investments

The amortized cost, gross unrealized gains, gross unrealized losses and fair values of interest-bearing securities, all of which are considered available-for-sale, by type of security were as follows (in millions):

Types of securities as of December 31, 2019	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 359	$ 1	$ —	$ 360
U.S. Treasury bills	—	—	—	—
Other government-related debt securities:				
U.S.	—	—	—	—
Foreign and other	—	—	—	—
Corporate debt securities:				
Financial	1,108	13	—	1,121
Industrial	824	10	—	834
Other	195	3	—	198
Residential-mortgage-backed securities	181	1	—	182
Other mortgage- and asset-backed securities	—	—	—	—
Money market mutual funds	5,250	—	—	5,250
Other short-term interest-bearing securities	289	—	—	289
Total available-for-sale investments	$ 8,206	$ 28	$ —	$ 8,234

Types of securities as of December 31, 2018	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 2,710	$ —	$ (47)	$ 2,663
U.S. Treasury bills	8,191	—	—	8,191
Other government-related debt securities:				
U.S.	112	—	(2)	110
Foreign and other	972	1	(41)	932
Corporate debt securities:				
Financial	2,778	—	(81)	2,697
Industrial	2,603	—	(99)	2,504
Other	583	—	(21)	562
Residential-mortgage-backed securities	1,458	—	(36)	1,422
Other mortgage- and asset-backed securities	483	—	(14)	469
Money market mutual funds	5,659	—	—	5,659
Other short-term interest-bearing securities	3,515	—	—	3,515
Total available-for-sale investments	$ 29,064	$ 1	$ (341)	$ 28,724

The fair values of available-for-sale investments by location in the Consolidated Balance Sheets were as follows (in millions):

	December 31,	
Consolidated Balance Sheets locations	2019	2018
Cash and cash equivalents	$ 5,360	$ 6,365
Marketable securities	2,874	22,359
Total available-for-sale investments	$ 8,234	$ 28,724

Cash and cash equivalents in the above table excludes bank account cash of $677 million and $580 million as of December 31, 2019 and 2018, respectively.

The fair values of available-for-sale investments by contractual maturity, except for mortgage- and asset-backed securities that do not have a single maturity date, were as follows (in millions):

	December 31,	
Contractual maturities	2019	2018
Maturing in one year or less	$ 5,629	$ 17,424
Maturing after one year through three years	2,304	3,356
Maturing after three years through five years	119	5,168
Maturing after five years through ten years	—	885
Mortgage- and asset-backed securities	182	1,891
Total available-for-sale investments	$ 8,234	$ 28,724

For the years ended December 31, 2019, 2018 and 2017, realized gains on interest-bearing securities were $92 million, $29 million and $147 million, respectively, and realized losses on interest-bearing securities were $36 million, $394 million and $213 million, respectively. Realized gains and losses on interest-bearing securities are recorded in Interest and other income, net, in the Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

As of December 31, 2019, aggregate gross unrealized losses of available-for-sale investments were not material. As of December 31, 2018, the fair values and gross unrealized losses of available-for-sale investments in an unrealized loss position aggregated by type and length of time that the securities have been in a continuous loss position were as follows (in millions):

	Less than 12 months		12 months or more	
Types of securities as of December 31, 2018	**Fair values**	**Unrealized losses**	**Fair values**	**Unrealized losses**
U.S. Treasury notes	$ 1,219	$ (21)	$ 1,444	$ (26)
Other government-related debt securities:				
U.S.	—	—	110	(2)
Foreign and other	631	(31)	240	(10)
Corporate debt securities:				
Financial	1,968	(59)	718	(22)
Industrial	1,898	(81)	529	(18)
Other	529	(20)	28	(1)
Residential-mortgage-backed securities	576	(14)	840	(22)
Other mortgage- and asset-backed securities	17	—	451	(14)
Total	$ 6,838	$ (226)	$ 4,360	$ (115)

The primary objective of our investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

We review our available-for-sale investments for other-than-temporary declines in fair value below our cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. The evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below our cost basis as well as adverse conditions related specifically to the security, such as any changes to the credit rating of the security and the intent to sell or whether we will more likely than not be required to sell the security before recovery of its amortized cost basis. Our assessment of whether a security is other-than-temporarily impaired could change in the future based on new developments or changes in assumptions related to that particular security. As of December 31, 2019 and 2018, we believe the cost bases for our available-for-sale investments were recoverable in all material respects.

Equity securities

We held investments in equity securities with readily determinable fair values of $303 million and $176 million as of December 31, 2019 and 2018, respectively, which are included in Other assets in the Consolidated Balance Sheets. Gains and losses recognized on equity securities with readily determinable fair values, including gains and losses recognized on sales, were not material for the years ended December 31, 2019, 2018 and 2017.

We held investments of $176 million and $222 million in equity securities without readily determinable fair values as of December 31, 2019 and 2018, respectively, which are included in Other assets in the Consolidated Balance Sheets. Adjustments to the carrying values of these securities were not material for the years ended December 31, 2019, 2018 and 2017.

Limited partnership investments

We held limited partnership investments of $320 million and $285 million as of December 31, 2019 and 2018, respectively, which are included in Other assets in the Consolidated Balance Sheets. These investments are measured by using the net asset values of the underlying investments as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of December 31, 2019, unfunded additional commitments to be made for these investments during the next several years were not material. Gains and losses recognized on our limited partnership investments were not material for the years ended December 31, 2019, 2018 and 2017.

10. Inventories

Inventories consisted of the following (in millions):

	December 31,	
	2019	2018
Raw materials	$ 358	$ 257
Work in process	2,227	1,660
Finished goods	999	1,023
Total inventories	$ 3,584	$ 2,940

11. Property, plant and equipment

Property, plant and equipment consisted of the following (dollar amounts in millions):

		December 31,	
	Useful life (in years)	2019	2018
Land	—	$ 263	$ 265
Buildings and improvements	10-40	3,757	3,616
Manufacturing equipment	8-12	2,655	2,418
Laboratory equipment	8-12	1,236	1,174
Capitalized software	3-5	1,154	1,124
Other	3-15	3,313	3,204
Construction in progress	—	907	953
Property, plant and equipment, gross		13,285	12,754
Less accumulated depreciation and amortization		(8,357)	(7,796)
Property, plant and equipment, net		$ 4,928	$ 4,958

During the years ended December 31, 2019, 2018 and 2017, we recognized depreciation and amortization expense associated with our property, plant and equipment of $635 million, $630 million and $604 million, respectively.

Geographic information

Certain geographic information with respect to property, plant and equipment, net (long-lived assets), was as follows (in millions):

	December 31,	
	2019	2018
United States	$ 2,433	$ 2,373
Puerto Rico	1,402	1,476
ROW	1,093	1,109
Total property, plant and equipment, net	$ 4,928	$ 4,958

12. Goodwill and other intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows (in millions):

	Years ended December 31,	
	2019	2018
Beginning balance	$ 14,699	$ 14,761
Addition from acquisitions	26	6
Currency translation adjustments	(22)	(68)
Ending balance	$ 14,703	$ 14,699

Other intangible assets

Other intangible assets consisted of the following (in millions):

	December 31,					
	2019			2018		
	Gross carrying amounts	Accumulated amortization	Other intangible assets, net	Gross carrying amounts	Accumulated amortization	Other intangible assets, net
Finite-lived intangible assets:						
Developed-product-technology rights	$ 25,575	$ (8,322)	$ 17,253	$ 12,573	$ (7,479)	$ 5,094
Licensing rights	3,761	(2,398)	1,363	3,772	(2,032)	1,740
Marketing-related rights	1,382	(965)	417	1,297	(1,019)	278
R&D technology rights	1,273	(947)	326	1,148	(872)	276
Total finite-lived intangible assets	31,991	(12,632)	19,359	18,790	(11,402)	7,388
Indefinite-lived intangible assets:						
IPR&D	54	—	54	55	—	55
Total other intangible assets	$ 32,045	$ (12,632)	$ 19,413	$ 18,845	$ (11,402)	$ 7,443

Developed-product-technology rights consists of rights related to marketed products acquired in acquisitions. Licensing rights consists primarily of contractual rights acquired in acquisitions to receive future milestone, royalty and profit-sharing payments; capitalized payments to third parties for milestones related to regulatory approvals to commercialize products; and up-front payments associated with royalty obligations for marketed products. Marketing-related rights consists primarily of rights related to the sale and distribution of marketed products. R&D technology rights pertains to technologies used in R&D that have alternative future uses. Developed-product-technology rights and marketing-related rights include assets acquired with the Otezla® acquisition. R&D technology rights includes assets acquired with the Nuevolution acquisition. See Note 2, Acquisitions.

IPR&D consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. All IPR&D projects have major risks and uncertainties associated with the timely and successful completion of the development and commercialization of product candidates, including our ability to confirm safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not permitted to market a human therapeutic without obtaining regulatory approvals, and such approvals require the completion of clinical trials that demonstrate that a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans as well as competitive product launches, affect the revenues a product can generate. Consequently, the eventual realized values, if any, of acquired IPR&D projects may vary from their estimated fair values. We review IPR&D projects for impairment annually, whenever events or

changes in circumstances indicate that the carrying amounts may not be recoverable and upon the establishment of technological feasibility or regulatory approval.

During the years ended December 31, 2019, 2018 and 2017, we recognized amortization associated with our finite-lived intangible assets of $1.4 billion, $1.3 billion and $1.3 billion, respectively. Amortization of intangible assets is included primarily in Cost of sales in the Consolidated Statements of Income. The total estimated amortization for our finite-lived intangible assets for the years ending December 31, 2020, 2021, 2022, 2023 and 2024, are $2.8 billion, $2.6 billion, $2.5 billion, $2.4 billion and $2.4 billion, respectively.

13. Leases

On January 1, 2019, we adopted a new accounting standard that amends the guidance for the accounting and reporting of leases. Certain required disclosures have been made on a prospective basis in accordance with the standard's guidance. See Note 1, Summary of significant accounting policies.

We lease certain facilities and equipment related primarily to administrative, R&D and sales and marketing activities. Leases with terms of 12 months or less are expensed on a straight-line basis over the term and are not recorded in the Consolidated Balance Sheets.

Most leases include one or more options to renew, with renewal terms that may extend the lease term up to seven years. The exercise of lease renewal options is at our sole discretion. In addition, some of our lease agreements include rental payments adjusted periodically for inflation. Our lease agreements neither contain residual value guarantees nor impose significant restrictions or covenants. We sublease certain real estate to third parties. Our sublease portfolio consists of operating leases from former R&D and administrative space.

The following table summarizes information related to our leases, all of which are classified as operating, included in our Consolidated Balance Sheets (in millions):

Consolidated Balance Sheets locations	December 31, 2019
Assets:	
Other assets	$ 469
Liabilities:	
Accrued liabilities	$ 140
Other noncurrent liabilities	388
Total lease liabilities	$ 528

The components of net lease costs were as follows (in millions):

Lease costs	Year ended December 31, 2019
Operating[1]	$ 204
Sublease income	(33)
Total net lease costs	$ 171

[1] Includes short-term leases and variable lease costs, which were not material for the year ended December 31, 2019.

Maturities of lease liabilities as of December 31, 2019, were as follows (in millions):

Maturity dates	Amounts
2020	$ 157
2021	150
2022	110
2023	88
2024	30
Thereafter	32
Total lease payments[1]	567
Less imputed interest	(39)
Present value of lease liabilities	$ 528

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(1) Includes future rental commitments for abandoned leases of $178 million. We expect to receive total future rental income of $141 million related to noncancelable subleases for abandoned facilities.

The weighted-average remaining lease term and weighted-average discount rate of our leases were 4.1 years and 3.3%, respectively, as of December 31, 2019.

Cash and noncash information related to our leases was as follows (in millions):

	Year ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows for operating leases	$ 148
ROU assets obtained in exchange for lease obligations:	
Operating leases	$ 163

As of December 31, 2019, we have entered into leases that have not yet commenced, with total undiscounted future lease payments of $306 million. Theses leases will commence between 2020 and 2021 with lease terms from 5 years to 15 years.

The following table summarizes minimum future rental commitments related to noncancelable operating leases under the prior lease guidance as of December 31, 2018 (in millions):

	Amounts
2019	$ 164
2020	126
2021	113
2022	64
2023	56
Thereafter	46
Total minimum operating lease commitments	$ 569

Included in the table above are future rental commitments for abandoned leases in the amount of $222 million. As of December 31, 2018, we expect to receive total future rental income of $203 million related to noncancelable subleases for abandoned facilities. Rental expenses on operating leases under the prior lease guidance for the years ended December 31, 2018 and 2017, were $166 million and $159 million, respectively.

14. Other current assets and accrued liabilities

Other current assets consisted of the following (in millions):

	December 31,	
	2019	2018
Prepaid expenses	$ 939	$ 907
Corporate partner receivables	485	444
Interest receivables	110	177
Other	354	266
Total other current assets	$ 1,888	$ 1,794

Accrued liabilities consisted of the following (in millions):

	December 31,	
	2019	2018
Sales deductions	$ 3,880	$ 3,170
Employee compensation and benefits	981	1,001
Dividends payable	946	914
Sales returns reserve	564	535
Other	2,140	2,242
Total accrued liabilities	$ 8,511	$ 7,862

15. Financing arrangements

Our borrowings consisted of the following (in millions):

	December 31,	
	2019	2018
5.70% notes due 2019 (5.70% 2019 Notes)	$ —	$ 1,000
1.90% notes due 2019 (1.90% 2019 Notes)	—	700
Floating Rate Notes due 2019	—	550
2.20% notes due 2019 (2.20% 2019 Notes)	—	1,400
2.125% €675 million notes due 2019 (2.125% 2019 euro Notes)	—	774
4.50% notes due 2020 (4.50% 2020 Notes)	300	300
2.125% notes due 2020 (2.125% 2020 Notes)	750	750
Floating Rate Notes due 2020	300	300
2.20% notes due 2020 (2.20% 2020 Notes)	700	700
3.45% notes due 2020 (3.45% 2020 Notes)	900	900
4.10% notes due 2021 (4.10% 2021 Notes)	1,000	1,000
1.85% notes due 2021 (1.85% 2021 Notes)	750	750
3.875% notes due 2021 (3.875% 2021 Notes)	1,750	1,750
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	1,402	1,433
2.70% notes due 2022 (2.70% 2022 Notes)	500	500
2.65% notes due 2022 (2.65% 2022 Notes)	1,500	1,500
3.625% notes due 2022 (3.625% 2022 Notes)	750	750
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	725	713
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
3.125% notes due 2025 (3.125% 2025 Notes)	1,000	1,000
2.00% €750 million notes due 2026 (2.00% 2026 euro Notes)	841	860
2.60% notes due 2026 (2.60% 2026 Notes)	1,250	1,250
5.50% £475 million notes due 2026 (5.50% 2026 pound sterling Notes)	630	606
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	928	893
6.375% notes due 2037 (6.375% 2037 Notes)	552	552
6.90% notes due 2038 (6.90% 2038 Notes)	291	291
6.40% notes due 2039 (6.40% 2039 Notes)	466	466
5.75% notes due 2040 (5.75% 2040 Notes)	412	412
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	974	974
5.65% notes due 2042 (5.65% 2042 Notes)	487	487
5.375% notes due 2043 (5.375% 2043 Notes)	261	261
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(868)	(896)
Fair value adjustments	296	(53)
Total carrying value of debt	29,903	33,929
Less current portion	(2,953)	(4,419)
Total long-term debt	$ 26,950	$ 29,510

There are no material differences between the effective interest rates and the coupon rates of any of our borrowings, except for the 4.563% 2048 Notes and the 4.663% 2051 Notes, which have effective interest rates of 6.3% and 5.6%, respectively.

Under the terms of all of our outstanding notes, except our Other notes due 2097, in the event of a change-in-control triggering event we may be required to purchase all or a portion of these debt securities at prices equal to 101% of the principal amounts of the notes plus accrued and unpaid interest. In addition, all of our outstanding notes —except our floating-rate notes, 0.41% 2023 Swiss franc Bonds and Other notes due 2097—may be redeemed at any time at our option—in whole or in part—at the principal amounts of the notes being redeemed plus accrued and unpaid interest and make-whole amounts, which are defined by the terms of the notes. Certain of the redeemable notes do not require the payment of make-whole amounts if redeemed during a specified period of time immediately prior to the maturity of the notes. Such time periods range from one month to six months prior to maturity.

Debt issuances

During the year ended December 31, 2017, we issued $4.5 billion principal amount of notes, consisting of the Floating Rate Notes due 2019, the 1.90% 2019 Notes, the Floating Rate Notes due 2020, the 2.20% 2020 Notes, the 2.65% 2022 Notes and the 3.20% 2027 Notes. We did not issue any debt or debt securities during the years ended December 31, 2019 and 2018.

As of December 31, 2019, we have a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. During the year ended December 31, 2017, we issued and repaid an aggregate of $12.3 billion of commercial paper and had a maximum outstanding balance of $1.5 billion under our commercial paper program. During the years ended December 31, 2019 and 2018, we did not issue any commercial paper.

Debt repayments

We made debt repayments during the years ended December 31, 2019, 2018 and 2017 as follows:

- In 2019, we repaid $4.5 billion of debt, including the $1.4 billion aggregate principal amount of the 2.20% 2019 Notes, the $1.0 billion aggregate principal amount of the 5.70% 2019 Notes, the €675 million aggregate principal amount ($864 million upon settlement of the related cross-currency swap) of the 2.125% 2019 euro Notes, the $700 million aggregate principal amount of the 1.90% 2019 Notes and the $550 million Floating Rate Notes due 2019.

- In 2018, we repaid $1.1 billion of debt, including the $500 million aggregate principal amount of the 6.15% 2018 Notes and the €550 million aggregate principal amount of the 4.375% 2018 Notes revalued at $621 million upon maturity.

- In 2017, we repaid $4.4 billion of debt, including the $605 million short-term floating-rate loan, the $1.25 billion aggregate principal amount of the 2.125% 2017 Notes, the $600 million aggregate principal amount of the Floating Rate Notes due 2017, the $850 million aggregate principal amount of the 1.25% 2017 Notes and the $1.1 billion aggregate principal amount of the 5.85% 2017 Notes.

Interest rate swaps

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted fixed-rate interest coupons for certain of our debt issuances to floating London Interbank Offered Rate (LIBOR)-based coupons over the lives of the respective notes. These interest rate swap contracts qualified and are designated as fair value hedges.

The effective interest rates on notes for which we have entered into interest rate swap contracts and the related notional amounts of these contracts were as follows (dollar amounts in millions):

		December 31,	
		2019	2018
Notes	Effective interest rates	Notional amounts	
2.20% 2019 Notes	LIBOR + 0.6%	$ —	$ 1,400
3.45% 2020 Notes	LIBOR + 1.1%	900	900
4.10% 2021 Notes	LIBOR + 1.7%	1,000	1,000
3.875% 2021 Notes	LIBOR + 2.0%	1,750	1,750
3.625% 2022 Notes	LIBOR + 1.6%	750	750
3.625% 2024 Notes	LIBOR + 1.4%	1,400	1,400
3.125% 2025 Notes	LIBOR + 0.9%	1,000	1,000
2.60% 2026 Notes	LIBOR + 0.3%	1,250	1,250
4.663% 2051 Notes	LIBOR + 0.0%	1,500	1,500
Total notional amounts		$ 9,550	$ 10,950

Cross-currency swaps

In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. The terms of these contracts effectively convert the interest payments and principal repayments on our 1.25% 2022 euro Notes, 0.41% 2023 Swiss franc Bonds, 2.00% 2026 euro Notes, 5.50% 2026 pound sterling Notes and 4.00% 2029 pound sterling Notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts have been designated as cash flow hedges. For information regarding the terms of these contracts, see Note 18, Derivative instruments.

Shelf registration statements and other facilities

In 2019, we amended and restated our $2.5 billion syndicated, unsecured, revolving credit agreement, which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $750 million with the agreement of the banks. Each bank that is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest for any amounts borrowed under this facility, based on our current credit rating, at (i) LIBOR plus 1% or (ii) the highest of (A) the syndication agent bank base commercial lending rate, (B) the overnight federal funds rate plus 0.50% or (C) one-month LIBOR plus 1%. The agreement contains provisions relating to the determination of successor rates to address the possible phase-out or unavailability of designated reference rates. As of December 31, 2019 and 2018, no amounts were outstanding under this facility.

In February 2020, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2023.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which requires that we maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2019.

Contractual maturities of debt obligations

The aggregate contractual maturities of all borrowings due subsequent to December 31, 2019, are as follows (in millions):

Maturity dates	Amounts
2020	$ 2,950
2021	3,500
2022	4,152
2023	1,474
2024	1,400
Thereafter	16,999
Total	$ 30,475

Interest costs

Interest costs are expensed as incurred except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest costs capitalized for the years ended December 31, 2019, 2018 and 2017, were not material. Interest paid, including the ongoing impact of interest rate and cross-currency swap contracts, during the years ended December 31, 2019, 2018 and 2017, was $1.3 billion, $1.5 billion and $1.3 billion, respectively.

16. Stockholders' equity

Stock repurchase program

Activity under our stock repurchase program, on a trade date basis, was as follows (in millions):

	Years ended December 31,					
	2019		2018		2017	
	Shares*	Dollars	Shares*	Dollars	Shares	Dollars
First quarter	15.9	$ 3,031	56.4	$ 10,787	3.4	$ 555
Second quarter	13.1	2,349	18.2	3,190	6.2	1,006
Third quarter	6.2	1,170	8.7	1,713	4.4	769
Fourth quarter	5.1	1,090	11.1	2,165	4.5	796
Total stock repurchases	40.2	$ 7,640	94.5	$ 17,855	18.5	$ 3,126

* Total shares do not add due to rounding.

In May 2019 and December 2019, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $5.0 billion and $4.0 billion, respectively. As of December 31, 2019, $6.5 billion remained available under our stock repurchase program.

Dividends

Our Board of Directors declared quarterly dividends per share of $1.45, $1.32 and $1.15, which were paid in each of the four quarters of 2019, 2018, and 2017, respectively.

Historically, we have declared dividends in December of each year, which were paid in the first quarter of the following fiscal year and in March, July and October, which were paid in the second, third and fourth quarters, respectively, of the same fiscal year. Additionally, on December 11, 2019, the Board of Directors declared a quarterly cash dividend of $1.60 per share of common stock, which will be paid on March 6, 2020, to all stockholders of record as of the close of business on February 14, 2020.

Accumulated other comprehensive income (loss)

The components of AOCI were as follows (in millions):

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2016	$ (610)	$ 282	$ (138)	$ (5)	$ (471)
Foreign currency translation adjustments	77	—	—	—	77
Unrealized gains (losses)	—	192	(46)	—	146
Reclassification adjustments to income	—	(638)	41	—	(597)
Other gains	—	—	—	5	5
Income taxes	4	158	(1)	—	161
Balance as of December 31, 2017	(529)	(6)	(144)	—	(679)
Cumulative effect of change in accounting principle, net of tax	—	—	(9)	—	(9)
Foreign currency translation adjustments	(141)	—	—	—	(141)
Unrealized gains (losses)	—	61	(556)	—	(495)
Reclassification adjustments to income	—	262	365	—	627
Other losses	—	—	—	(2)	(2)
Income taxes	—	(76)	6	—	(70)
Balance as of December 31, 2018	(670)	241	(338)	(2)	(769)
Foreign currency translation adjustments	(48)	—	—	—	(48)
Unrealized gains	—	127	424	—	551
Reclassification adjustments to income	—	(211)	(56)	—	(267)
Other losses	—	—	—	(5)	(5)
Income taxes	—	18	(8)	—	10
Balance as of December 31, 2019	$ (718)	$ 175	$ 22	$ (7)	$ (528)

With respect to the table above, income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for cash flow hedges were a $28 million expense and a $46 million benefit in 2019, a $21 million expense and a $55 million expense in 2018 and a $68 million expense and a $226 million benefit in 2017, respectively. Income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for available-for-sale securities were a $22 million expense and a $14 million benefit in 2019, a $9 million benefit and a $3 million expense in 2018 and a $9 million expense and an $8 million benefit in 2017, respectively.

Reclassifications out of AOCI and into earnings were as follows (in millions):

Components of AOCI	Years ended December 31, 2019	2018	2017	Consolidated Statements of Income locations
Cash flow hedges:				
Foreign currency contract gains (losses)	$ 101	$ (21)	$ 65	Product sales
Cross-currency swap contract gains (losses)	110	(241)	574	Interest and other income, net
Forward interest rate contract losses	—	—	(1)	Interest expense, net
	211	(262)	638	Income before income taxes
	(46)	55	(226)	Provision for income taxes
	$ 165	$ (207)	$ 412	Net income
Available-for-sale securities:				
Net realized gains (losses)	$ 56	$ (365)	$ (41)	Interest and other income, net
	(14)	3	(8)	Provision for income taxes
	$ 42	$ (362)	$ (49)	Net income

Other

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. As of December 31, 2019 and 2018, no shares of preferred stock were issued or outstanding.

17. Fair value measurement

To estimate the fair value of our financial assets and liabilities, we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing an asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing an asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access

Level 2 — Valuations for which all significant inputs are observable either directly or indirectly—other than Level 1 inputs

Level 3 — Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

The fair values of each major class of the Company's financial assets and liabilities measured at fair value on a recurring basis were as follows (in millions):

Fair value measurement as of December 31, 2019, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	$ 360	$ —	$ —	$ 360
U.S. Treasury bills	—	—	—	—
Other government-related debt securities:				
U.S.	—	—	—	—
Foreign and other	—	—	—	—
Corporate debt securities:				
Financial	—	1,121	—	1,121
Industrial	—	834	—	834
Other	—	198	—	198
Residential-mortgage-backed securities	—	182	—	182
Other mortgage- and asset-backed securities	—	—	—	—
Money market mutual funds	5,250	—	—	5,250
Other short-term interest-bearing securities	—	289	—	289
Equity securities	303	—	—	303
Derivatives:				
Foreign currency contracts	—	224	—	224
Cross-currency swap contracts	—	66	—	66
Interest rate swap contracts	—	259	—	259
Total assets	$ 5,913	$ 3,173	$ —	$ 9,086
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 31	$ —	$ 31
Cross-currency swap contracts	—	315	—	315
Interest rate swap contracts	—	—	—	—
Contingent consideration obligations	—	—	61	61
Total liabilities	$ —	$ 346	$ 61	$ 407

Fair value measurement as of December 31, 2018, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	$ 2,663	$ —	$ —	$ 2,663
U.S. Treasury bills	8,191	—	—	8,191
Other government-related debt securities:				
U.S.	—	110	—	110
Foreign and other	—	932	—	932
Corporate debt securities:				
Financial	—	2,697	—	2,697
Industrial	—	2,504	—	2,504
Other	—	562	—	562
Residential-mortgage-backed securities	—	1,422	—	1,422
Other mortgage- and asset-backed securities	—	469	—	469
Money market mutual funds	5,659	—	—	5,659
Other short-term interest-bearing securities	—	3,515	—	3,515
Equity securities	176	—	—	176
Derivatives:				
Foreign currency contracts	—	182	—	182
Cross-currency swap contracts	—	170	—	170
Interest rate swap contracts	—	56	—	56
Total assets	$ 16,689	$ 12,619	$ —	$ 29,308
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 26	$ —	$ 26
Cross-currency swap contracts	—	401	—	401
Interest rate swap contracts	—	149	—	149
Contingent consideration obligations	—	—	72	72
Total liabilities	$ —	$ 576	$ 72	$ 648

Interest-bearing and equity securities

The fair values of our U.S. Treasury securities, money market mutual funds and equity securities are based on quoted market prices in active markets, with no valuation adjustment.

As of December 31, 2019, our corporate debt securities are investment grade and have maturity dates of three years or less from the balance sheet date. Our corporate debt securities portfolio has weighted-average credit ratings of A– or equivalent by Standard & Poor's Financial Services LLC (S&P) or Moody's Investors Service, Inc. (Moody's), and A by Fitch Ratings, Inc. (Fitch). We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry-standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

Our residential-mortgage-backed-securities portfolio is composed entirely of senior tranches with credit ratings of AAA by S&P, Moody's or Fitch. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry-standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or

similar securities; issuer credit spreads; benchmark securities; prepayment or default projections based on historical data; and other observable inputs.

We value our other short-term interest-bearing securities at amortized cost, which approximates fair value given their near-term maturity dates.

Derivatives

All of our foreign currency forward and option derivative contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, the LIBOR, swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. These inputs, when applicable, are at commonly quoted intervals. See Note 18, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. See Note 18, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by using an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include LIBOR, swap rates and obligor credit default swap rates. See Note 18, Derivative instruments.

Contingent consideration obligations

As a result of our acquisitions, we have incurred contingent consideration obligations. The contingent consideration obligations are recorded at their fair values by using probability-adjusted discounted cash flows, and we revalue these obligations each reporting period until the related contingencies have been resolved. The fair value measurements of these obligations are based on significant unobservable inputs related to licensing rights and product candidates acquired in business combinations, and they are reviewed quarterly by management in our R&D and commercial sales organizations. Changes in the fair values of contingent consideration obligations are recognized in Other operating expenses in the Consolidated Statements of Income. Changes in the carrying amounts of contingent consideration obligations for the years ended December 31, 2019 and 2018, were not material. During the year ended December 31, 2017, we recorded a $110 million reduction to contingent consideration obligations due substantially to amounts associated with the Dezima Pharma B.V. (Dezima) acquisition, discussed below.

As a result of our acquisition of K-A in 2018, we are obligated to make single-digit royalty payments to Kirin contingent upon sales of brodalumab. See Note 2, Acquisitions.

As a result of our acquisition of Dezima in 2015, we are obligated to pay its former shareholders up to $1.25 billion of additional consideration contingent upon achieving certain development and sales-related milestones and low single-digit royalties on net product sales above a certain threshold for AMG 899, an IPR&D asset. The fair values of the contingent consideration obligations had an aggregate value of $110 million at acquisition. During 2017, we decided to discontinue the internal development of AMG 899 and accordingly, we reduced from $116 million to $0 the related contingent consideration liabilities and recognized an impairment charge of $400 million on the IPR&D asset in Other operating expenses in the Consolidated Statements of Income. The remeasurement of these liabilities and the impairment charge are included in Other items, net, in the Consolidated Statements of Cash Flows.

As a result of our acquisition of BioVex Group Inc. in 2011, we are obligated to pay its former shareholders up to $325 million upon achieving separate regulatory and sales-related milestones with regard to IMLYGIC® (talimogene laherparepvec) if certain sales thresholds are met within specified periods of time.

During the years ended December 31, 2019 and 2018, there were no transfers of assets or liabilities between fair value measurement levels, and there were no material remeasurements to the fair values of assets and liabilities that are not measured at fair value on a recurring basis, except with respect to the 2018 discontinuance of the internal development of a program that resulted in an impairment of an IPR&D asset of $330 million, which was recognized in Other operating expenses in the Consolidated Statements of Income and included in Other items, net, in the Consolidated Statements of Cash Flows.

Summary of the fair values of other financial instruments

Cash equivalents

The fair values of cash equivalents approximate their carrying values due to the short-term nature of such financial instruments.

Borrowings

We estimated the fair values of our borrowings by using Level 2 inputs. As of December 31, 2019 and 2018, the aggregate fair values of our borrowings were $33.7 billion and $35.0 billion, respectively, and the carrying values were $29.9 billion and $33.9 billion, respectively.

18. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we use or have used certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We do not use derivatives for speculative trading purposes.

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates associated primarily with our euro-denominated international product sales. Increases and decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are offset partially by corresponding increases and decreases in the cash flows from our international operating expenses resulting from these foreign currency exchange rate movements. To further reduce our exposure to foreign currency exchange rate fluctuations with regard to our international product sales, we enter into foreign currency forward and option contracts to hedge a portion of our projected international product sales primarily over a three-year time horizon, with, at any given point in time, a higher percentage of nearer-term projected product sales being hedged than in successive periods.

As of December 31, 2019, 2018 and 2017, we had outstanding foreign currency forward contracts with aggregate notional amounts of $5.0 billion, $4.5 billion and $4.6 billion, respectively. As of December 31, 2018 and 2017 we had outstanding foreign currency option contracts with aggregate notional amounts of $21 million and $74 million, respectively, and no such outstanding contracts as of December 31, 2019. We have designated these foreign currency forward and foreign currency option contracts, which are primarily euro based, as cash flow hedges. Accordingly, we report the unrealized gains and losses on these contracts in AOCI in the Consolidated Balance Sheets, and we reclassify them to Product sales in the Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term debt denominated in foreign currencies, we enter into cross-currency swap contracts. Under the terms of such contracts, we paid euros, pounds sterling and Swiss francs and received U.S. dollars for the notional amounts at the inception of the contracts; and based on these notional amounts, we exchange interest payments at fixed rates over the lives of the contracts by paying U.S. dollars and receiving euros, pounds sterling and Swiss francs. In addition, we will pay U.S. dollars to and receive euros, pounds sterling and Swiss francs from the counterparties at the maturities of the contracts for these same notional amounts. The terms of these contracts correspond to the related hedged debt, thereby effectively converting the interest payments and principal repayment on the debt from euros, pounds sterling and Swiss francs to U.S. dollars. We have designated these cross-currency swap contracts as cash flow hedges. Accordingly, the unrealized gains and losses on these contracts are reported in AOCI in the Consolidated Balance Sheets and reclassified to Interest and other income, net, in the Consolidated Statements of Income in the same periods during which the hedged debt affects earnings.

The notional amounts and interest rates of our cross-currency swaps as of December 31, 2019, were as follows (notional amounts in millions):

	Foreign currency			U.S. dollars	
Hedged notes	**Notional amounts**		**Interest rates**	**Notional amounts**	**Interest rates**
1.25% 2022 euro Notes	€	1,250	1.3 %	$ 1,388	3.2 %
0.41% 2023 Swiss franc Bonds	CHF	700	0.4 %	$ 704	3.4 %
2.00% 2026 euro Notes	€	750	2.0 %	$ 833	3.9 %
5.50% 2026 pound sterling Notes	£	475	5.5 %	$ 747	6.0 %
4.00% 2029 pound sterling Notes	£	700	4.0 %	$ 1,111	4.5 %

During the year ended December 31, 2019, our 2.125% 2019 euro Notes matured, and the related cross-currency swaps were settled.

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Consolidated Balance Sheets and are amortized into Interest expense, net, in the Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the year ended December 31, 2019, and amounts expected to be recognized during the subsequent 12 months are not material.

The unrealized gains and losses recognized in AOCI for our derivative instruments designated as cash flow hedges were as follows (in millions):

	Years ended December 31,		
Derivatives in cash flow hedging relationships	**2019**	**2018**	**2017**
Foreign currency contracts	$ 148	$ 348	$ (402)
Cross-currency swap contracts	(21)	(287)	581
Forward interest rate contracts	—	—	13
Total unrealized gains	$ 127	$ 61	$ 192

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified for and were designated as fair value hedges. These interest rate swap contracts effectively convert fixed-rate coupons to floating-rate LIBOR-based coupons over the terms of the related hedge contracts. As of December 31, 2019 and 2018, we had interest rate swap contracts with aggregate notional amounts of $9.6 billion and $11.0 billion, respectively, that hedge certain portions of our long-term debt issuances.

For interest rate swap contracts that qualify for and are designated as fair value hedges, we recognize in Interest expense, net, in the Consolidated Statements of Income the unrealized gain or loss on the derivative resulting from the change in fair value during the period, as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. If a hedging relationship involving an interest rate swap contract is terminated, the gain or loss realized on contract termination is recorded as an adjustment to the carrying value of the debt and amortized into Interest expense, net, over the remaining life of the previously hedged debt.

The hedged liabilities and related cumulative-basis adjustments for fair value hedges of those liabilities were recorded in the Consolidated Balance Sheets as follows (in millions):

	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
	December 31,		December 31,	
Consolidated Balance Sheets locations	2019	2018	2019	2018
Current portion of long-term debt	$ 903	$ 2,396	$ 4	$ (3)
Long-term debt	$ 8,814	$ 9,361	$ 292	$ (50)

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(1) Current portion of long-term debt includes $1.0 billion of carrying value with discontinued hedging relationships as of December 31, 2018. Long-term debt includes $136 million and $137 million of carrying value with discontinued hedging relationships as of December 31, 2019 and 2018, respectively.

(2) Current portion of long-term debt includes $3 million of hedging adjustments on discontinued hedging relationships as of December 31, 2018. Long-term debt includes $36 million and $37 million of hedging adjustments on discontinued hedging relationships as of December 31, 2019 and 2018, respectively.

Impact of hedging transactions

The following tables summarize the amounts recorded in income and expense line items and the effects thereon from fair value and cash flow hedging, including discontinued hedging relationships (in millions):

	Year ended December 31, 2019		
	Product sales	Interest and other income, net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 22,204	$ 753	$ (1,289)
The effects of cash flow and fair value hedging:			
Gains on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ 101	$ —	$ —
Cross-currency swap contracts	$ —	$ 110	$ —
(Losses) gains on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ (349)
Derivatives designated as hedging instruments	$ —	$ —	$ 352

	Year ended December 31, 2018		
	Product sales	Interest and other income, net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 22,533	$ 674	$ (1,392)
The effects of cash flow and fair value hedging:			
Losses on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ (21)	$ —	$ —
Cross-currency swap contracts	$ —	$ (241)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ 65
Derivatives designated as hedging instruments	$ —	$ —	$ (42)

	Year ended December 31, 2017		
	Product sales	Interest and other income, net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 21,795	$ 928	$ (1,304)
The effects of cash flow and fair value hedging:			
Gains (losses) on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ 65	$ —	$ —
Cross-currency swap contracts	$ —	$ 574	$ —
Forward interest rate contracts	$ —	$ —	$ (1)
Gains (losses) on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ 127
Derivatives designated as hedging instruments	$ —	$ —	$ (85)

[1] (Losses) gains on hedged items do not completely offset gains (losses) on the related designated hedging instruments due to amortization of the cumulative amounts of fair value hedging adjustments included in the carrying amount of the hedged debt for discontinued hedging relationships.

No portions of our cash flow hedge contracts were excluded from the assessment of hedge effectiveness. As of December 31, 2019, we expected to reclassify $47 million of net gains on our foreign currency and cross-currency swap contracts out of AOCI and into earnings during the next 12 months.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations in certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. Most of these exposures are hedged on a month-to-month basis. As of December 31, 2019, 2018 and 2017, the total notional amounts of these foreign currency forward contracts were $1.2 billion, $737 million and $757 million, respectively. Gains and losses recognized in earnings for our derivative instruments not designated as hedging instruments were not material for the years ended December 31, 2019, 2018 and 2017.

The fair values of derivatives included in the Consolidated Balance Sheets were as follows (in millions):

	Derivative assets		Derivative liabilities	
December 31, 2019	**Consolidated Balance Sheets locations**	**Fair values**	**Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 223	Accrued liabilities/ Other noncurrent liabilities	$ 31
Cross-currency swap contracts	Other current assets/ Other assets	66	Accrued liabilities/ Other noncurrent liabilities	315
Interest rate swap contracts	Other current assets/ Other assets	259	Accrued liabilities/ Other noncurrent liabilities	—
Total derivatives designated as hedging instruments		548		346
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	1	Accrued liabilities	—
Total derivatives not designated as hedging instruments		1		—
Total derivatives		$ 549		$ 346

	Derivative assets		Derivative liabilities	
December 31, 2018	**Consolidated Balance Sheets locations**	**Fair values**	**Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 181	Accrued liabilities/ Other noncurrent liabilities	$ 26
Cross-currency swap contracts	Other current assets/ Other assets	170	Accrued liabilities/ Other noncurrent liabilities	401
Interest rate swap contracts	Other current assets/ Other assets	56	Accrued liabilities/ Other noncurrent liabilities	149
Total derivatives designated as hedging instruments		407		576
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	1	Accrued liabilities	—
Total derivatives not designated as hedging instruments		1		—
Total derivatives		$ 408		$ 576

Our derivative contracts that were in liability positions as of December 31, 2019, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our, or the surviving entity's, creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right but not the obligation to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the

contracts may be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

The cash flow effects of our derivative contracts in the Consolidated Statements of Cash Flows are included in Net cash provided by operating activities, except for the settlement of notional amounts of cross-currency swaps, which are included in Net cash used in financing activities.

19. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See Part I, Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations.* We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote.

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Our legal proceedings involve various aspects of our business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing, in which we could incur a liability, our opponents seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process, which in complex proceedings of the sort we face often extend for several years. As a result, none of the matters described in this filing, in which we could incur a liability, have progressed sufficiently through discovery and/or the development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain recent developments concerning our legal proceedings and other matters are discussed below:

Abbreviated New Drug Application (ANDA) Patent Litigation

KYPROLIS® (carfilzomib) ANDA Patent Litigation

Onyx Therapeutics, Inc. v. Cipla Limited, et al.

Between October 2016 and April 2018, Onyx Therapeutics, Inc. (Onyx Therapeutics, a wholly-owned subsidiary of Amgen), filed separate lawsuits in the U.S. District Court for the District of Delaware (the Delaware District Court) against: (1) Cipla Limited and Cipla USA, Inc. (collectively, Cipla); (2) Sagent Pharmaceuticals, Inc. (Sagent); (3) Breckenridge Pharmaceutical, Inc. (Breckenridge); and (4) Fresenius Kabi, USA LLC, Fresenius Kabi USA, Inc., Fresenius Kabi Pharmaceuticals Holding, Inc. and Fresenius Kabi Oncology Limited; (5) Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.; (6) MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (collectively, MSN); (7) Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL); (8) Qilu Pharma, Inc. and Qilu Pharmaceutical Co. Ltd. (collectively, Qilu); (9) Apotex Inc. and Apotex Corp. (Apotex); (10) InnoPharma, Inc. (InnoPharma); and (11) Aurobindo Pharma USA, Inc., each for infringement of one or more of our following patents, which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) for KYPROLIS®: U.S. Patent Nos. 7,232,818 (the '818 Patent), 7,417,042 (the '042 Patent), 7,491,704 (the '704 Patent), 7,737,112 (the '112 Patent), 8,129,346 (the '346 Patent), 8,207,125 (the '125 Patent), 8,207,126 (the '126 Patent), 8,207,127 (the '127 Patent) and 8,207,297 (the '297 Patent). Each of these lawsuits were based on each defendant's submission of an ANDA seeking U.S. Food and Drug Administration (FDA) approval to market a generic version of KYPROLIS®. In each lawsuit, Onyx Therapeutics sought an order of the Delaware District Court making any FDA approval of the respective defendant's ANDA effective no earlier than the expiration of the applicable patents.

The Delaware District Court consolidated these lawsuits for purposes of discovery into a single case, *Onyx Therapeutics, Inc. v. Cipla Limited, et al.*

In 2017, by stipulation with Onyx Therapeutics, Fresenius Kabi Pharmaceuticals Holding, Inc. and Fresenius Kabi Oncology Limited were dismissed from the lawsuit, leaving Fresenius Kabi, USA LLC and Fresenius Kabi USA, Inc. (collectively, Fresenius) as the remaining Fresenius defendants. In September 2017 and February 2018, respectively, by joint stipulation with Onyx Therapeutics, Teva Pharmaceutical Industries Ltd. and Teva

Pharmaceuticals USA, Inc. were each dismissed from the lawsuit and in February 2018, Qilu was dismissed from the lawsuit by joint stipulation between Onyx Therapeutics and Qilu.

Between April and July of 2018, the Delaware District Court entered orders on stipulations between Onyx Therapeutics and each of Apotex, DRL, Sagent, Fresenius, Breckenridge, Aurobindo Pharma USA, Inc., Cipla and InnoPharma, respectively, that each defendant infringes the ’042, ’112, ’125, ’126 and ’127 Patents. Onyx Therapeutics provided those defendants, either through a stipulated order or other agreement, a covenant that it would not assert patent infringement of the ’818,’704,’346 and ’297 Patents against certain of the respective defendants’ ANDA applications and products. In June 2018, the Delaware District Court entered an order on a stipulation between Onyx Therapeutics and MSN that MSN infringes the ’112 Patent. In December 2018, Apotex, DRL, Fresenius, InnoPharma, Sagent, Breckenridge, Aurobindo Pharma USA, Inc. and Cipla amended their responses to the complaints to add the defense of unclean hands and to seek declarations of unenforceability of the asserted patents based on allegations of inequitable conduct. In January 2019, MSN amended its responses to the complaints to add the defense of unclean hands.

On January 11, 2019, Onyx Therapeutics filed a separate lawsuit in the Delaware District Court against Breckenridge for infringement of the ’042, ’112 and ’125 Patents in connection with its ANDA that seeks approval to market generic versions of KYPROLIS®. On March 4, 2019, the Delaware District Court entered an order on a stipulation between Onyx Therapeutics and Breckenridge, providing that Breckenridge infringes the asserted claims of the ’042, ’112 and ’125 Patents, and consolidated this lawsuit against Breckenridge into the existing consolidated case, *Onyx Therapeutics, Inc. v. Cipla Limited, et al.*, for all purposes.

On May 6, 2019, the Delaware District Court commenced trial in the *Onyx Therapeutics, Inc. v. Cipla Limited, et al*. consolidated case. During trial, the Delaware District Court signed consent judgments filed by Onyx Therapeutics and each of Aurobindo Pharma USA, Inc., InnoPharma, Sagent, Apotex, Fresenius, DRL and Breckenridge, in which the parties stipulated to entry of: (1) judgment dismissing with prejudice all of the parties’ claims, counterclaims, affirmative defenses and demands; and (2) an injunction prohibiting infringement of the ’042, ’112 and ’125 Patents by the manufacture, use, sale, offer to sell or importation into the United States of the applicable defendant’s carfilzomib product unless specifically authorized pursuant to the applicable confidential settlement agreement. During trial, the Delaware District Court also entered a consent judgment between Onyx Therapeutics and MSN, in which the parties stipulated to entry of: (1) judgment dismissing with prejudice all of the parties’ claims, counterclaims, affirmative defenses and demands; and (2) an injunction prohibiting infringement of the ’112 Patent by the manufacture, use, sale, offer to sell or importation into the United States of MSN’s carfilzomib product unless specifically authorized pursuant to the confidential settlement agreement. On May 16, 2019, trial concluded between Onyx Therapeutics and the lone remaining defendant, Cipla. On January 17, 2020, the Delaware District Court issued an order advising the parties that the court expects to issue its post-trial opinion by, on or about, March 31, 2020.

Otezla® (apremilast) ANDA Patent Litigation

Celgene Corp. v. Sandoz Inc., et al.

Beginning in June 2018, Celgene filed 19 separate lawsuits in the U.S. District Court for the District of New Jersey (the New Jersey District Court) against Alkem Laboratories Ltd. (Alkem); Amneal Pharmaceuticals LLC; Annora Pharma Private Ltd. and Hetero USA Inc. (collectively, Hetero); Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. (collectively, Aurobindo); Cipla Limited (Cipla Ltd); DRL; Emcure Pharmaceuticals Ltd. and Heritage Pharmaceuticals Inc. (collectively, Emcure); Glenmark Pharmaceuticals Ltd. (Glenmark); Macleods Pharmaceuticals Ltd. (Macleods); Mankind Pharma Ltd. (Mankind); MSN Laboratories Private Limited; Pharmascience Inc. (Pharmascience); Prinston Pharmaceutical Inc. (Prinston); Sandoz Inc.; Shilpa Medicare Ltd. (Shilpa); Teva Pharmaceuticals USA, Inc. and Actavis LLC (collectively, Actavis); Torrent Pharmaceuticals Ltd. (Torrent); Unichem Laboratories, Ltd. (Unichem); and Zydus Pharmaceuticals (USA) Inc., each for infringement of one or more of the following patents: U.S. Patent Nos. 6,962,940 (the ’940 Patent); 7,208,516 (the ’516 Patent); 7,427,638 (the ’638 Patent); 7,659,302 (the ’302 Patent); 7,893,101 (the ’101 Patent); 8,455,536 (the ’536 Patent); 8,802,717 (the ’717 Patent); 9,018,243 (the ’243 Patent) and 9,872,854 (the ’854 Patent), which are listed in the Orange Book for Otezla®. Each of the defendants is seeking to market a generic version of Otezla® before expiration of the asserted patents. The New Jersey District Court consolidated these 19 lawsuits for discovery and case management purposes into a single case, *Celgene Corp. v. Sandoz Inc., et al.* Each lawsuit seeks an order of the New Jersey District Court making any FDA approval of the respective defendant’s ANDA effective no earlier than the expiration of the applicable patents.

Between August 8, 2018 and August 30, 2018, Celgene filed amended complaints against Alkem, Amneal Pharmaceuticals LLC, Aurobindo, Cipla Ltd, DRL, Glenmark, Pharmascience, Sandoz Inc., Actavis, Unichem and Zydus Pharmaceuticals (USA) Inc. additionally asserting U.S. Patent No. 9,724,330 (the ’330 Patent), which is listed in the Orange Book for Otezla®. Between October 15 and November 27, 2018, Celgene filed amended complaints

against Alkem, Amneal Pharmaceuticals LLC, Hetero, Aurobindo, Cipla Ltd, DRL, Emcure, Glenmark, Macleods, Mankind, MSN Laboratories Private Limited, Pharmascience, Prinston, Sandoz Inc., Actavis, Torrent, Unichem and Zydus Pharmaceuticals (USA) Inc. additionally asserting U.S. Patent No. 10,092,541 (the ’541 Patent), which is listed in the Orange Book for Otezla®. Between March 1, 2019 and April 4, 2019, Celgene filed amended complaints against Hetero, MSN Laboratories Private Limited and Emcure for infringement of one or more of the above-listed patents. On October 1, 2019, Celgene filed an amended complaint against Mankind for infringement of the ’940, ’302, ’536, ’243 and ’330 Patents. On October 8, 2019, Celgene filed a separate lawsuit against Zydus Pharmaceuticals (USA) Inc. in the New

Jersey District Court for infringement of U.S. Patent Nos. 8,093,283 (the ’283 Patent) and 8,629,173 (the ’173 Patent), which are not listed in the Orange Book for Otezla®. On December 19, 2019, the New Jersey District Court consolidated this lawsuit for discovery and case management purposes into the existing consolidated case, *Celgene Corp. v. Sandoz Inc., et al*.

Each defendant has filed an answer to the above-listed complaints and amended complaints disputing infringement and/or validity of the patents asserted against it. Along with their answers, each of Alkem, Hetero, Cipla Ltd, DRL, Emcure, Glenmark, Macleods, Mankind, Pharmascience, Sandoz Inc., Shilpa, Actavis, Torrent, Unichem and Zydus Pharmaceuticals (USA) Inc. filed declaratory judgment counterclaims asserting that some or all of the patents are not infringed and/or are invalid. In August 2019, based on a joint request by Celgene and Glenmark, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, having made, using, selling, offering to sell, importing, or distributing of Glenmark’s apremilast product during the term of the ’940, ’638, ’302, ’101, ’536, ’243, ’330 and’541 Patents, unless authorized pursuant to a confidential settlement agreement.

On December 20, 2019, following Amgen’s acquisition of the patents-in-suit and the new drug application for Otezla®, Amgen and Celgene jointly moved the New Jersey District Court for an order (1) substituting Amgen for Celgene for all purposes in this litigation; (2) terminating Celgene from this litigation; and (3) changing the consolidated case caption and all related actions to reflect Amgen as the sole plaintiff. Defendants have opposed the motion.

Sensipar® (cinacalcet) ANDA Patent Litigation

Amgen Inc. v. Amneal Pharmaceuticals LLC, et al. (formerly, Amgen Inc. v. Aurobindo Pharma Ltd. et al.) Consolidated Case

Beginning in September 2016, Amgen filed 14 separate lawsuits in the Delaware District Court for infringement of our U.S. Patent No. 9,375,405 (the ’405 Patent) against a number of manufacturers of purported generic versions of our Sensipar® product. In February 2017, the Delaware District Court consolidated these 14 lawsuits into a single case, *Amgen Inc. v. Aurobindo Pharma Ltd. et al.* In June 2017, Amgen filed an additional lawsuit in the Delaware District Court for infringement of the ’405 Patent which was consolidated into *Amgen Inc. v. Aurobindo Pharma Ltd. et al*. in August 2017. The ’405 Patent is entitled “Rapid Dissolution Formulation of a Calcium Receptor-Active Compound” and expires in 2026. All defendants responding to the complaint denied infringement and sought judgment that the ’405 Patent is invalid and/or not infringed.

Between September and November of 2017, Amgen filed, and the Delaware District Court signed, stipulated dismissals of the lawsuit against Micro Labs Ltd. and Micro Labs USA, Inc., and the lawsuit against Apotex, as well as consent judgments filed by Amgen and each of (1) Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, Sun); (2) Ajanta Pharma Limited and Ajanta Pharma USA, Inc.; (3) Hetero USA Inc., Hetero Labs Ltd. and Hetero Labs Ltd. Unit V; and (4) Breckenridge. Each consent judgment stipulated to an entry of judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of or distribution into the United States of the respective defendant’s cinacalcet product during the term of the ’405 Patent unless specifically authorized pursuant to the confidential settlement agreement.

On March 5, 2018, the Delaware District Court commenced trial on the infringement claims and defenses in the *Amgen Inc. v. Aurobindo Pharma Ltd. et al.* consolidated lawsuit against the defendants that remained in the lawsuit, collectively consisting of (1) Watson Laboratories, Inc. and Actavis Pharma, Inc. (collectively, Watson); (2) Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); (3) Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, Zydus); and (4) Piramal Healthcare UK Limited (Piramal). Just prior to trial, the Delaware District Court signed consent judgments filed by Amgen and each of Cipla, and Strides Pharma Global Pte Limited and Strides Pharma, Inc. (collectively, Strides), and a consent judgment filed by Amgen and Aurobindo. In each consent judgment, the parties stipulated to an entry of judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of or distribution into the United States of the applicable defendant’s cinacalcet product during the term of the ’405 Patent unless specifically authorized pursuant to the applicable confidential settlement agreement. Just prior to trial, the Delaware District Court also entered orders dismissing each of DRL and Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan), on stipulations between Amgen and such parties, respectively, subject to the terms of confidential settlement agreements.

On July 27, 2018, the Delaware District Court issued a trial order finding on the infringement claims and defenses in the *Amgen Inc. v. Aurobindo Pharma Ltd. et al.* consolidated lawsuit that Zydus infringes the ’405 Patent

and that Amneal, Piramal and Watson do not infringe the ’405 Patent. On August 24, 2018, the Delaware District Court issued an order dismissing, without prejudice, the invalidity counterclaims of Amneal, Piramal and Watson and entered judgment of noninfringement of the ’405 Patent in favor of Amneal, Piramal and Watson. On September 20, 2018, Amgen filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court). On October 9, 2018, the Delaware District Court dismissed, without prejudice, the invalidity counterclaims of Zydus and entered judgment of infringement of the ’405 Patent by Zydus in favor of Amgen, including an order that the effective date of the FDA approval of Zydus’ generic version of Sensipar® shall be no earlier

than the expiry date of our ’405 Patent. On October 11, 2018, Zydus filed a notice of appeal to the Federal Circuit Court, and on October 24, 2018, the Federal Circuit Court consolidated the appeals of Zydus and Amgen.

In December 2018, the FDA approved Watson’s generic version of Sensipar® and Watson’s parent company, Teva Pharmaceutical Industries Ltd. (Teva), began selling its product at-risk notwithstanding that the appeals were pending at the Federal Circuit Court. On January 2, 2019, Amgen, Watson and Teva entered into a settlement agreement in which Teva agreed to stop selling its generic product until the mid-year 2021, or earlier under certain circumstances and to pay Amgen an undisclosed amount. On January 9, 2019, Watson and Amgen filed a motion asking the Delaware District Court to vacate its final judgment of noninfringement as to Watson and to enter a proposed consent judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the making, having made, using, selling, offering to sell, or distributing Watson’s cinacalcet product in the United States or importing Watson’s cinacalcet product into the United States, consistent with the confidential settlement agreement. On January 11, 2019, the Federal Circuit Court stayed the pending appeal as to Watson in order for the Delaware District Court to rule on the motion of Watson and Amgen. On January 18, 2019 and January 23, 2019, respectively, Cipla and Sun filed oppositions to the motion of Watson and Amgen.

On March 19, 2019, Amgen filed an emergency motion for an injunction pending appeal, seeking an order from the Delaware District Court enjoining defendant Piramal from making, using, selling, offering for sale or importing its generic cinacalcet product. Amgen’s motion follows an announcement that Slate Run Pharmaceuticals LLC (Slate Run), in partnership with Piramal, had begun selling Piramal’s generic cinacalcet product at-risk notwithstanding the appeals pending at the Federal Circuit Court. On April 15, 2019, the Delaware District Court signed an order enjoining Piramal and Slate Run from selling their generic cinacalcet product until certain events occur related to a decision by the Federal Circuit Court on the parties’ appeal. The order has no effect on the product that Piramal and Slate Run had already sold to third parties.

On March 26, 2019, the Delaware District Court denied the joint motion for indicative ruling of Watson and Amgen. On April 10, 2019, Amgen filed an appeal to the Federal Circuit Court. On April 29, 2019, the Federal Circuit Court lifted the stay of Amgen’s appeal of the judgment of noninfringement as to Watson and consolidated it with Amgen’s appeal of the Delaware District Court’s denial of the joint motion for indicative ruling. On July 17, 2019, Amgen filed a motion requesting the Federal Circuit Court to vacate the Delaware District Court’s noninfringement judgment with respect to Watson and direct entry of the parties’ proposed consent judgment. On July 18, 2019, Cipla filed an opposition to Amgen’s motion and also moved to participate in the appeal as either an intervenor or as *amicus curiae*. On September 13, 2019, the Federal Circuit Court denied Amgen’s motion, lifted the stay of the briefing schedule which had been stayed pending disposition of Amgen’s motion to vacate and granted Cipla permission to file a brief as *amicus curiae*.

On January 7, 2020, the Federal Circuit Court issued an opinion affirming the judgment of noninfringement with respect to Piramal, affirming the judgment of infringement with respect to Zydus and vacating and remanding to the Delaware District Court for further consideration the judgment of noninfringement with respect to Amneal.

Amgen Inc. v. The ACME Laboratories Ltd.

On September 11, 2019, Amgen filed a lawsuit in the Delaware District Court against The ACME Laboratories Ltd. (ACME) for infringement of Amgen’s ’405 Patent. On November 20, 2019, the Delaware District Court signed a consent judgment filed by Amgen and ACME in which the parties stipulated to an entry of judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of or distribution into the United States of ACME’s cinacalcet product during the term of the ’405 Patent unless specifically authorized pursuant to the confidential settlement agreement.

ENBREL (etanercept) Patent Litigation

Immunex Corporation, et al. v. Samsung Bioepis Co., Ltd.

On April 30, 2019, two affiliates of Amgen Inc., Immunex Corporation and Amgen Manufacturing, Limited (collectively, Amgen), along with Hoffmann-La Roche Inc. (Roche), filed a lawsuit in the New Jersey District Court against Samsung Bioepis Co., Ltd. (Bioepis). This lawsuit stems from Bioepis’ submission of an application for FDA licensure of an etanercept product as biosimilar to Amgen’s ENBREL. Amgen and Roche have asserted infringement of five patents: U.S. Patent Nos. 8,063,182 (the ’182 Patent); 8,163,522 (the ’522 Patent); 7,915,225 (the ’225 Patent); 8,119,605 (the ’605 Patent); and 8,722,631 (the ’631 Patent). By their complaint, Amgen and Roche seek an injunction to prohibit Bioepis from commercializing its biosimilar etanercept product in the United States prior to the expiry of such patents. On August 5, 2019, defendant Bioepis responded to the complaint, denying infringement and seeking judgment that the patents-in-suit are invalid, unenforceable and/or not infringed. On January 9, 2020 and

subject to the terms of a confidential stipulation and court order of January 6, 2020, the New Jersey District Court entered a consent injunction that prohibits Bioepis from making, using, offering to sell, selling or importing into the United States Bioepis' etanercept product. Amgen and Bioepis entered into an agreement with respect to an injunction regarding etanercept as

set out in the New Jersey District Court's order of January 6, 2020. On January 15, 2020, the New Jersey District Court entered an order administratively staying the case pursuant to a joint request of Amgen and Bioepis.

Immunex Corporation, et al. v. Sandoz Inc., et al.

On February 26, 2016, two affiliates of Amgen Inc., Immunex Corporation and Amgen Manufacturing, Limited (collectively, Amgen), along with Hoffmann-La Roche Inc. (Roche), filed a lawsuit in the New Jersey District Court against Sandoz Inc., Sandoz International GmbH and Sandoz GmbH (collectively, Sandoz). This lawsuit stems from Sandoz's submission of an application for FDA licensure of an etanercept product as biosimilar to Amgen's ENBREL. Amgen and Roche have asserted infringement of five patents: the '182, '522, '225, '605 and '631 Patents. By their complaint, Amgen and Roche seek an injunction to prohibit Sandoz from commercializing its biosimilar etanercept product in the United States prior to the expiry of such patents. All Sandoz defendants responded by denying infringement and/or asserting that the patents at issue are invalid. On August 11, 2016, and subject to the terms of a confidential stipulation, the New Jersey District Court entered a preliminary injunction prohibiting Sandoz from making, using, importing, selling or offering for sale Sandoz's etanercept product. On August 30, 2016, the FDA approved Sandoz's Erelzi™, a biosimilar to ENBREL.

On September 10, 2018, the New Jersey District Court entered an order that the making, using, offering to sell or selling in the United States or the importation into the United States by Sandoz of Sandoz's biosimilar etanercept product infringes the '182 and '522 Patents. The New Jersey District Court held a bench trial from September 11, 2018 to September 25, 2018, focusing on Sandoz's challenges to the validity of these patents. On August 9, 2019, the New Jersey District Court issued its decision upholding the validity of the '182 and '522 Patents. On October 8, 2019, by stipulation of Amgen and Sandoz, the New Jersey District Court entered final judgment and a permanent injunction prohibiting Sandoz from making, using, importing, selling or offering for sale Sandoz's etanercept product, and, on the same day, Sandoz appealed the final judgment to the Federal Circuit Court. Following a motion by Sandoz, the Federal Circuit Court ordered an expedited briefing schedule for the appeal and briefing on appeal has been completed. Oral argument has been set for March 4, 2020.

Repatha® (evolocumab) Patent Litigation

Amgen Inc., et al. v. Sanofi, et al.

In October 2014, Amgen initiated a series of lawsuits that were consolidated by the Delaware District Court in December 2014 into a single case against Sanofi, Sanofi-Aventis U.S. LLC and Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc. (collectively, Sanofi) and Regeneron Pharmaceuticals, Inc. (Regeneron), addressing seven of our patents: U.S. Patent Nos. 8,563,698; 8,829,165 (the '165 Patent); 8,859,741 (the '741 Patent); 8,871,913; 8,871,914; 8,883,983; and 8,889,834. These patents describe and claim monoclonal antibodies to proprotein convertase subtilisin/kexin type 9 (PCSK9). By its complaints, Amgen seeks an injunction to prevent the infringing manufacture, use and sale of Sanofi and Regeneron's alirocumab, a monoclonal antibody targeting PCSK9. On January 29, 2016, the Delaware District Court granted Amgen's motion to amend the complaint to add its affiliates, Amgen Manufacturing, Limited and Amgen USA Inc., as plaintiffs and to add the allegation that Sanofi and Regeneron's infringement of Amgen's patents is willful.

On February 22, 2016, the Delaware District Court entered a stipulated order finding alirocumab and the drug product containing it, PRALUENT®, infringe certain of Amgen's patents, including claims 2, 7, 9, 15, 19 and 29 of the '165 Patent and claim 7 of the '741 Patent. On March 18, 2016, the Delaware District Court entered judgment in favor of Amgen following a five-day jury trial and a unanimous jury verdict that these patent claims from the '165 Patent and the '741 Patent are all valid. On January 3, 2017, the Delaware District Court denied Sanofi and Regeneron's post-trial motions seeking a new trial and for judgment as a matter of law, and on January 5, 2017, granted Amgen's motion for a permanent injunction prohibiting the infringing manufacture, use, sale, offer for sale or import of alirocumab in the United States.

On January 12, 2017, Sanofi and Regeneron filed an appeal of the judgment and the permanent injunction to the Federal Circuit Court. On February 8, 2017, following a motion by Sanofi and Regeneron, the Federal Circuit Court entered a stay of the permanent injunction during the pendency of the appeal. On October 5, 2017, the Federal Circuit Court reversed in part the judgment of the Delaware District Court and remanded for a new trial two of the patent validity defenses (lack of written description and enablement of the claimed inventions), and affirmed the Delaware District Court's judgment of infringement of claims 2, 7, 9, 15, 19 and 29 of the '165 Patent and claim 7 of the '741 Patent and the third patent validity defense (finding that the claimed inventions were not obvious to a person of ordinary skill in the field of the patents).

On December 6, 2017, Amgen petitioned the Federal Circuit Court for rehearing *en banc*, which was denied. The Federal Circuit Court issued a March 2, 2018 mandate returning the case to the Delaware District Court for a new trial on two of Sanofi and Regeneron's challenges to the validity of our patents (lack of written description and enablement of the claimed inventions) and for further consideration of a permanent injunction. On July 23, 2018, Amgen filed a petition for certiorari with the U.S. Supreme Court seeking review of the Federal Circuit Court's conclusion that the judgment affirming the validity of Amgen's patents was based, in part, on an erroneous application of the law of written description. On January 7, 2019, the U.S. Supreme

Court denied Amgen's petition for certiorari. On remand, the Delaware District Court scheduled a new trial on Sanofi and Regeneron's challenges to the validity of our patents based on lack of written description and enablement of the claimed inventions. The Delaware District Court also entered judgment on the pleadings for Sanofi and Regeneron on Amgen's claim of willful infringement.

On February 25, 2019, a jury of the Delaware District Court unanimously upheld the validity of claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent. The jury also found that claims 7 and 15 of the '165 Patent meet the enablement requirement, but are invalid for failure to meet the written description requirement. On March 18, 2019, Sanofi and Regeneron filed post-trial motions seeking to reverse judgment as a matter of law or for a new trial with respect to claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent, and Amgen filed a motion for a permanent injunction. On June 6, 13 and 21, 2019, the Delaware District Court held evidentiary hearings on Amgen's motion for a permanent injunction against PRALUENT®. On August 28, 2019, the Delaware District Court ruled on the post-trial motions, denying Sanofi and Regeneron's request for a new trial and their request to reverse the jury verdict that the '165 Patent and the '741 Patent provide written description support for the claimed inventions. The Delaware District Court also ruled as a matter of law that claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent are invalid for failing to meet the enablement requirement, overturning the jury verdict. On October 23, 2019, Amgen filed a notice of appeal to the Federal Circuit Court.

Patent Disputes in the International Region

On February 24, 2016, the European Patent Office (EPO) granted European Patent No. 2,215,124 (EP 2,215,124) to Amgen. This patent describes and claims monoclonal antibodies to PCSK9 and methods of treatment. On February 24, 2016, Sanofi filed an opposition to the patent in the EPO seeking to invalidate it. In November 2016, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A. and Sanofi Winthrop Industrie S.A. filed a joint opposition against Amgen's patent, and each of Eli Lilly and Company, Regeneron and Strawman Ltd. also filed oppositions to Amgen's patent. On November 30, 2018, the EPO confirmed the validity of Amgen's EP 2,215,124, which has been appealed to the Technical Board of Appeal. A two-day hearing is scheduled to begin on March 24, 2020.

We are also involved in and expect future involvement in additional disputes regarding our PCSK9 patents in other jurisdictions and regions, including matters filed against us and that we have filed in the United Kingdom, Germany, France, The Netherlands, Italy, Spain and Japan.

NEUPOGEN® (filgrastim)/Neulasta® (pegfilgrastim) Patent Litigation

Amgen Inc., et al. v. Accord BioPharma (formerly, Amgen Inc., et al. v. Apotex Inc., et al.)

On August 7, 2018, Amgen Inc. and its wholly-owned subsidiary, Amgen Manufacturing, Limited (collectively, Amgen), filed a lawsuit in the U.S. District Court for the Southern District of Florida (the Florida District Court) against Apotex for infringement of U.S. Patent No. 9,856,287 (the '287 Patent) in accordance with the patent provisions of the Biologics Price Competition and Innovation Act (BPCIA). This lawsuit stemmed from Apotex's submissions of applications for FDA licensure of a pegfilgrastim product as biosimilar to Amgen's Neulasta® and a filgrastim product as biosimilar to Amgen's NEUPOGEN®. By its complaint, Amgen sought, among other remedies, an injunction prohibiting Apotex from infringing the '287 Patent. On April 18, 2019, Apotex answered the complaint including counterclaims seeking declaratory judgments of noninfringement and invalidity. On August 27, 2019, the Florida District Court granted an unopposed motion to substitute Accord BioPharma in place of Apotex. On November 14, 2019, the parties entered into a settlement agreement resolving all issues between the parties. On November 15, 2019, the Florida District Court issued an order dismissing the case without prejudice.

Apotex PTAB Challenge

On February 17, 2017, the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office (USPTO) granted Apotex's petition to institute inter partes review (IPR) proceeding of the of U.S. Patent No. 8,952,138 (the '138 Patent), challenging claims of the '138 Patent as unpatentable. On May 22, 2017, Amgen filed its response. The PTAB issued a final decision holding all but one claim of the '138 Patent as unpatentable, and on March 16, 2018, Apotex filed a request for rehearing. On May 20, 2019, the PTAB issued a decision denying Apotex's request for rehearing on the PTAB's finding and *sua sponte* amending the final decision with a finding that the one remaining claim in Amgen's '138 Patent is unpatentable. On July 22, 2019, Amgen filed a notice of appeal to the Federal Circuit Court with respect to all claims held to be unpatentable. On August 5, 2019, Apotex provided notice that it would not participate in the appeal. On September 16, 2019, the USPTO filed a notice of intervention on the appeal.

Amgen Inc., et al. v. Kashiv Biosciences, LLC, et al.

On March 8, 2018, Amgen Inc. and its wholly-owned subsidiary, Amgen Manufacturing, Limited (collectively, Amgen), filed a lawsuit in the New Jersey District Court against Kashiv Biosciences, LLC, formerly known as Adello Biologics, LLC (Kashiv). This lawsuit stemmed from Kashiv's submission of an application for FDA licensure of a filgrastim product as biosimilar to Amgen's NEUPOGEN®. Amgen initially asserted infringement of 17 of our patents. Amgen sought an injunction to prohibit Kashiv from commercializing its biosimilar filgrastim product in the United States prior to the expiry of these patents. Following discovery in October 2018, Amgen filed a first amended complaint in the New Jersey District Court adding as defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc. and reducing the number of patents-in-suit from 17 to 4: U.S. Patent Nos. 8,940,878 (the '878 Patent); the '138 Patent; 9,643,997 (the '997 Patent); and the '287 Patent. Kashiv responded to the first amended complaint, seeking judgment that our patents-in-suit are not infringed by Kashiv's biosimilar filgrastim product and that our patents are invalid.

On November 20, 2019, Amgen and Kashiv entered into a settlement agreement resolving all issues between the parties in the New Jersey District Court and PTAB proceedings (discussed below). On November 25, 2019, the New Jersey District Court entered the dismissal of all claims and counterclaims without prejudice.

Apotex/Kashiv PTAB Challenge

On April 19, 2019, the PTAB instituted post grant proceedings against the '287 Patent in response to a petition filed by Apotex and Kashiv alleging the claimed invention is unpatentable. On October 4, 2019, the PTAB granted judgement adverse to Apotex and the review proceedings continued with Kashiv as the sole petitioner until December 6, 2019, when the PTAB dismissed the post grant review pursuant to the joint motion to terminate the proceeding due to settlement.

Kashiv PTAB Challenge

In a separate challenge, on September 11, 2019, the PTAB instituted IPR proceedings in response to a petition filed by Kashiv challenging the patentability of each claim of the '878 Patent and the '997 Patent. On December 6, 2019, pursuant to a joint motion to terminate the proceedings due to settlement, the PTAB dismissed the IPR proceedings.

Amgen Inc., et al. v. Pfizer Inc. et al.

On July 18, 2018, Amgen Inc. and its wholly owned subsidiary, Amgen Manufacturing, Limited (collectively, Amgen), filed a lawsuit in the Delaware District Court against Pfizer Inc. and Hospira Inc. (collectively, Pfizer). This lawsuit stems from Pfizer's submission of an application for FDA licensure of a filgrastim product as biosimilar to Amgen's NEUPOGEN®. Amgen has asserted infringement of the '997 Patent and seeks, among other remedies, injunctive relief to prohibit Pfizer from infringing the '997 Patent. On July 20, 2018, the FDA approved Pfizer's NIVESTYM™, a biosimilar to NEUPOGEN®, which was subsequently launched in October 2018.

On August 9, 2018, Pfizer answered the complaint and counterclaimed seeking a declaration that Pfizer does not infringe Amgen's '997 Patent and that the patent is invalid. On March 22, 2019, Amgen filed an amended complaint against Pfizer in the Delaware District Court narrowing the patent claims at issue in the infringement dispute and adding a request for damages. On April 11, 2019, Pfizer answered Amgen's amended complaint including counterclaims seeking declaratory judgments of noninfringement and invalidity. Trial is scheduled to commence on June 15, 2020.

Amgen Inc., et al. v. Hospira Inc. et al.

On February 11, 2020, Amgen Inc. and its wholly owned subsidiary, Amgen Manufacturing, Limited (collectively, Amgen), filed a lawsuit in the Delaware District Court against Hospira, Inc. and Pfizer Inc. (collectively, Pfizer). This lawsuit stems from Pfizer's submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen's Neulasta®. Amgen has asserted infringement of U.S. Patent No. 8,273,707 (the '707 Patent) and seeks, among other remedies, injunctive relief to prohibit Pfizer from infringing the '707 Patent.

Fresenius PTAB Challenge

On June 8, 2019, Fresenius Kabi USA, LLC and Fresenius Kabi SwissBioSim GmbH filed a petition seeking to institute IPR proceeding before the PTAB to challenge the patentability of the '997 Patent. On December 10, 2019, the PTAB instituted the IPR proceeding.

In a separate action, on December 20, 2019, Fresenius Kabi USA, LLC and Fresenius Kabi SwissBioSim GmbH filed a petition seeking to institute IPR proceeding before the PTAB to challenge the patentability of the ’287 Patent. Amgen’s preliminary response is due in March 2020 after which the PTAB will have three months to render a decision on whether to institute trial proceedings.

Amgen Inc., et al. v. Tanvex BioPharma USA, Inc., et al.

On July 23, 2019, Amgen and its wholly owned subsidiary, Amgen Manufacturing, Limited, filed a lawsuit in the U.S. District Court for the Southern District of California (the California Southern District Court) against Tanvex BioPharma USA, Inc., Tanvex BioPharma, Inc. and Tanvex Biologics Corporation (collectively, Tanvex) for infringement of the ’287 Patent in accordance with the patent provisions of the BPCIA. This lawsuit stemmed from Tanvex’s submission of an application for FDA licensure of a filgrastim product as biosimilar to Amgen’s NEUPOGEN®. By its complaint, Amgen sought, among other remedies, an injunction prohibiting Tanvex from infringing the ’287 Patent. On September 23, 2019, Tanvex responded to Amgen’s complaint, denying infringement and seeking judgment of noninfringement and invalidity of Amgen’s ’287 Patent. On December 17, 2019, Amgen and Tanvex entered into a settlement agreement resolving all issues between the parties. On December 20, 2019, the California Southern District Court dismissed all claims and counterclaims without prejudice.

EPOGEN® (epoetin alfa) Patent Litigation

Amgen Inc., et al. v. Hospira, Inc.

On September 18, 2015, Amgen Inc. and its wholly owned subsidiary, Amgen Manufacturing, Limited (collectively, Amgen), filed a lawsuit in the Delaware District Court against Hospira, Inc. (Hospira), a subsidiary of Pfizer Inc., for infringement of Amgen’s U.S. Patent Nos. 5,856,298 (the ’298 Patent) and 5,756,349 (the ’349 Patent) in accordance with the patent provisions of the BPCIA and for a declaration that Hospira has failed to comply with certain requirements of the BPCIA. This lawsuit stems from the submission by Hospira under the BPCIA of an application for FDA licensure of an epoetin product as biosimilar to Amgen’s EPOGEN®. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Hospira from using or selling infringing cells and/or product manufactured during the ’298 or the ’349 Patent terms and enjoining Hospira from commencing commercial marketing of any biosimilar epoetin product until a date that is at least 180 days after Hospira provides legally effective notice to Amgen. On August 19, 2016, Hospira responded to the complaint denying patent infringement and any violation of the BPCIA and seeking judgment that the patents-in-suit are invalid and not infringed by Hospira. On January 23, 2017, the Delaware District Court entered an order construing the claims of the ’349 and ’298 Patents and holding that two claims of the ’298 Patent are invalid for failure to properly narrow the claim on which they depend. On September 22, 2017, after a five-day trial, the jury returned a verdict finding the ’298 Patent valid and infringed by Hospira and the ’349 Patent not infringed. The jury awarded Amgen $70 million in damages for Hospira’s infringement. On October 23, 2017, Hospira moved for judgment as a matter of law of noninfringement and invalidity of the ’298 Patent or, in the alternative, for reduction of the damage award or a new trial on the ’298 Patent, which was denied on August 27, 2018. On May 15, 2018, the FDA approved Hospira’s RETACRIT®, a biosimilar to EPOGEN®, which was subsequently launched on November 14, 2018. On September 11, 2018, the Delaware District Court entered final judgment.

On October 3, 2018, Hospira filed a notice of appeal to the Federal Circuit Court and on October 15, 2018, Amgen filed a notice of cross-appeal. On December 16, 2019, the Federal Circuit Court affirmed the final judgment of the Delaware District Court. On January 15, 2020, Hospira petitioned the Federal Circuit Court for rehearing *en banc*.

Litigation relating to our Biosimilar Products

AMJEVITA™ (adalimumab-atto)/AMGEVITA™ Patent Litigation

Coherus BioSciences, Inc. v. Amgen Inc.

On January 24, 2019, Coherus BioSciences, Inc. (Coherus) filed a lawsuit in the Delaware District Court that the formulation of AMJEVITA™ infringes three patents: U.S. Patent Nos. 10,155,039; 10,159,732; and 10,159,733. By its complaint, Coherus sought, among other remedies, injunctive relief prohibiting patent infringement. On April 18, 2019, Amgen responded to the lawsuit denying patent infringement and seeking judgment that the patents-in-suit are invalid, unenforceable and/or not infringed by Amgen. On November 26, 2019, the Delaware District Court entered a stipulated order dismissing Coherus’ infringement claims with prejudice and Amgen’s defenses and counterclaims as moot.

KANJINTI™ (trastuzumab-anns) Patent Litigation*

Genentech, Inc. v. Amgen Inc.

On June 21, 2018, Genentech Inc. (Genentech) and City of Hope filed a lawsuit in the Delaware District Court alleging Amgen's infringement of 37 patents by Amgen's submission of an application for FDA licensure of KANJINTI™, Amgen's biosimilar version of Genentech's Herceptin® (trastuzumab). On July 19, 2018, Genentech, City of Hope and Amgen filed a joint stipulation to dismiss certain of the patents from the lawsuit and Genentech and City of Hope filed an amended complaint narrowing its allegations of infringement to 18 of the 37 patents. Among other remedies, Genentech and City of Hope seek injunctive relief prohibiting patent infringement. On August 23, 2018, Genentech and City of Hope moved to dismiss Amgen's unenforceability counterclaims and affirmative defense. On November 7, 2018, in accordance with the scheduling order issued by the Delaware District Court, Genentech and City of Hope reduced the number of asserted patents from 18 to 10. On January 17, 2019, Genentech and the City of Hope filed a second amended complaint that removed one of the remaining 10 asserted patents and added a different patent.

On July 10, 2019, Genentech filed a motion asking the Delaware District Court for a temporary restraining order and preliminarily injunction prohibiting Amgen from commercially launching, marketing or selling KANJINTI™ until the Delaware District Court renders a decision on the merits of Genentech's asserted U.S. Patent Nos. 6,627,196; 7,371,379; and 10,160,811. Following Amgen's opposition, on July 18, 2019, the Delaware District Court denied Genentech's motion. On July 19, 2019, Genentech filed a notice of appeal and a motion requesting the Federal Circuit Court to enter an injunction prohibiting Amgen from continuing with its launch of KANJINTI™ until final resolution of Genentech's appeal. On July 24, 2019, the Delaware District Court entered an order dismissing City of Hope as a party to the lawsuit and dismissing with prejudice Genentech's claims for infringement of a number of expired patents, leaving eight patents asserted by Genentech in the litigation. On August 7, 2019, the Federal Circuit Court denied Genentech's motion for an injunction pending appeal. Briefing of the appeal has been completed and argument has been scheduled for March 3, 2020. On September 4, 2019, Genentech filed its third amended complaint adding a demand for a jury trial and an award of damages for infringement. On September 23, 2019, the Delaware District Court ordered a stipulated dismissal with prejudice of all claims for infringement of certain asserted patents, leaving four patents asserted by Genentech in the litigation. On September 24, 2019, Amgen filed its answer to Genentech's third amended complaint denying infringement of any valid patent claim. The jury trial has been rescheduled to begin on April 20, 2020.

MVASI™ (bevacizumab-awwb) Patent Litigation*

Genentech, Inc. and City of Hope v. Amgen Inc.

On October 6 and October 18, 2017, Genentech and City of Hope filed separate lawsuits in the Delaware District Court respectively alleging Amgen's infringement of (i) 24 of the 27 patents listed by Genentech in the BPCIA exchange and (ii) 25 of the same 27 patents, in each case by Amgen's submission for FDA licensure of MVASI™ as biosimilar to Genentech's Avastin® (bevacizumab) and for noncompliance with certain provisions of the BPCIA. On December 6, 2017, Genentech and City of Hope amended their complaints to allege that Amgen will also infringe newly issued U.S. Patent No. 9,795,672. On April 17, 2018, the Delaware District Court granted Amgen's motion to dismiss certain claims by Genentech and City of Hope that Amgen had not complied with the BPCIA.

Amgen responded to the complaints on May 1 and June 5, 2018, respectively, denying patent infringement and any violation of the BPCIA and seeking judgment that the patents-in-suit are invalid, unenforceable and/or not infringed by Amgen. On May 22 and June 19, 2018, respectively, Genentech and City of Hope moved to dismiss from each case all of Amgen's counterclaims and certain of Amgen's defenses.

On August 31, 2018, in accordance with the scheduling order issued by the Delaware District Court, Genentech and City of Hope reduced the number of asserted patents in each lawsuit to eight, asserting the same patents in each case. On October 22, 2018, the two cases were consolidated by the Delaware District Court. On August 22, 2019 and October 29, 2019, by stipulation of the parties, the Delaware District Court entered judgment of noninfringement, in each instance, with respect to one of the patents asserted in the consolidated lawsuit, leaving a total of six remaining patents asserted by Genentech in the litigation. Trial is scheduled to begin on November 30, 2020.

On February 11, 2020, the Delaware District Court granted Genentech's motion to dismiss Amgen's counterclaim seeking judgment that U.S. Patent Nos. 6,610,516 and 7,323,553 are invalid, unenforceable and not infringed based on the Court's finding that Genentech has represented that it does not plan to assert those patents against Amgen's MVASI™ product. On February 12, 2020, the Delaware District Court denied Amgen's motion for leave to amend its answer, affirmative defenses and counterclaims to add affirmative defenses and counterclaims that

U.S. Patent No. 8,574,869 is unenforceable for inequitable conduct and unclean hands. The Delaware District Court also denied Genentech's motion for leave to amend its complaint to add allegation of infringement of U.S. Patent No. 9,714,293.

* Registered in the United States.

Genentech, Inc. and City of Hope v. Immunex Rhode Island Corp. and Amgen Inc.

On March 29, 2019, Genentech and City of Hope filed a lawsuit against Amgen in the Delaware District Court alleging infringement of 14 patents. All but two of the 14 patents asserted in this lawsuit have already been the subject of litigation pending among these parties in this court relating to Amgen's submission of the application that led to the FDA licensure of MVASI™ as biosimilar to Genentech's Avastin® (bevacizumab). Among other remedies, Genentech and City of Hope are seeking injunctive relief. On July 10, 2019, Genentech, alleging that Amgen's notice of commercial marketing pursuant to the BPCIA is insufficient, filed motions asking the Delaware District Court for a temporary restraining order and enforcement of the BPCIA to prohibit Amgen from commercially marketing MVASI™ until Amgen has provided new notice and waited until the expiry of the notice period. Following Amgen's opposition, on July 18, 2019, the Delaware District Court denied Genentech's motions. On July 19, 2019, Genentech filed a notice of appeal and a motion requesting the Federal Circuit Court to enter an injunction prohibiting Amgen from marketing MVASI™ until final resolution of Genentech's appeal, which was denied on August 16, 2019. Briefing of the appeal has been completed.

Breach of Contract Action

Cipla Ltd. et al. v. Amgen Inc.

On January 8, 2019, Cipla filed a separate lawsuit in the Delaware District Court against Amgen seeking a declaration that provisions of its settlement agreement with Amgen have been triggered by Teva's at-risk launch of Watson's generic version of Sensipar®, giving Cipla a right to market its own generic version under its settlement agreement with Amgen. Cipla's complaint also alleges antitrust violations by Amgen. The portions of the complaint covering Cipla's settlement agreement were filed with the court under seal and remain confidential.

On March 11, 2019, following an announcement by Cipla that it had begun selling its generic cinacalcet product in the United States, Amgen filed a counterclaim and related motion for preliminary injunction in the Delaware District Court. Amgen's motion seeks to prohibit Cipla from making, having made, using, selling, offering to sell or distributing its generic cinacalcet product in breach of the settlement agreement between the parties. On May 2, 2019, the Delaware District Court denied Amgen's motion for preliminary injunction, and Amgen filed its notice of appeal in the United States Court of Appeals for the Third Circuit (the Third Circuit Court of Appeals). On May 3, 2019, Amgen filed a motion for injunction pending appeal in the Delaware District Court, which was denied on May 9, 2019. On May 13, 2019, Amgen filed a motion for injunction pending appeal and expedited briefing in the Third Circuit Court of Appeals. On May 23, 2019, the Third Circuit Court of Appeals denied the motion for injunction pending appeal and granted the request for expedited briefing. On July 16, 2019, the Third Circuit Court of Appeals affirmed the Delaware District Court's decision denying Amgen's motion for a preliminary injunction. On October 15, 2019, Amgen moved to dismiss Cipla's antitrust and fraud claims brought in the Delaware District Court for lack of standing and failure to state a claim. On December 6, 2019, Cipla filed its response to Amgen's complaint and, on January 10, 2020, Amgen filed its response.

Novartis Pharma AG v. Amgen Inc.

On April 4, 2019, Amgen filed a lawsuit in the U.S. District Court for the Southern District of New York against Novartis Pharma AG seeking a declaratory judgment that Novartis Pharma AG materially breached two collaboration agreements related to the development and commercialization of Aimovig® (erenumab-aooe) due to Novartis Pharma AG's affiliate Sandoz Gmbh entering into a contract manufacturing agreement with Alder BioPharmaceuticals, Inc. (Alder) related to eptinezumab, an expected direct competitor to Aimovig® and entrant in the calcitonin gene-related peptide (CGRP)-related migraine therapy market. Amgen seeks to terminate its collaboration agreements with Novartis Pharma AG and also seeks damages from Novartis Pharma AG for breach of contract and negligent misrepresentation. Also on April 4, 2019, Novartis Pharma AG initiated a separate lawsuit against Amgen in the same court seeking declaratory judgment that Novartis Pharma AG, alternatively, did not materially breach the collaboration agreements or, even if it did breach the collaboration agreements, such breach was not material and has been cured, and that Amgen may not terminate the collaboration agreements. On April 8, 2019, Amgen answered Novartis Pharma AG's complaint and filed counterclaims seeking a declaratory judgment that Novartis Pharma AG materially breached the collaboration agreements due to its affiliate Sandoz Gmbh entering into the contract manufacturing agreement with Alder. In its counterclaim, Amgen seeks to terminate its collaboration agreements with Novartis Pharma AG and also seeks damages from Novartis Pharma AG for breach of contract and negligent misrepresentation. On July 16, 2019, Novartis Pharma AG filed an amended complaint adding a claim for breach of contract alleging Novartis Pharma AG is owed amounts associated with 2018 budget overruns and Amgen responded with a counterclaim alleging additional breaches by Novartis Pharma AG of the collaboration agreements. On September 17, 2019 and October 8, 2019, Novartis Pharma AG and Amgen, respectively, each filed its motion for

judgment on the pleadings. Amgen was granted leave to file its amended counterclaims on February 3, 2020 and filed its Amended Answer to Novartis' First Amended Complaint and Second Amended Counterclaims for Affirmative Relief on February 4, 2020 to add a fraudulent inducement claim.

Antitrust Class Action

Sensipar® Antitrust Class Actions

From February 21, 2019, to April 10, 2019, four plaintiffs filed putative class action lawsuits against Amgen and various entities affiliated with Teva alleging anticompetitive conduct in connection with settlements between Amgen and manufacturers of generic cinacalcet product. Two of those actions were brought in the Delaware District Court, captioned *UFCW Local 1500 Welfare Fund v. Amgen Inc., et al.* (February 21, 2019) (Local 1500) and *Cesar Castillo, Inc. v. Amgen Inc., et al.* (February 26, 2019) (Castillo). The third action was brought in the New Jersey District Court, captioned *Teamsters Local 237 Welfare Fund, et al. v. Amgen Inc., et al.* (March 14, 2019) (Local 237) and the fourth action was brought in the U.S. District Court for the Eastern District of Pennsylvania (the Eastern Pennsylvania District Court), captioned *KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. v. Amgen Inc., et al* (April 10, 2019) (KPH).

Each of the lawsuits is brought on behalf of a putative class of direct or indirect purchasers of Sensipar® and alleges that the plaintiffs have overpaid for Sensipar® as a result of Amgen's conduct that allegedly improperly delayed market entry by manufacturers of generic cinacalcet products. The lawsuits focus predominantly on the settlement among Amgen, Watson and Teva of the parties' patent infringement litigation. Each of the lawsuits seeks, among other things, treble damages, equitable relief and attorneys' fees and costs. On April 10, 2019, the plaintiff in the KPH lawsuit filed a motion seeking to have the four lawsuits consolidated and designated as a multidistrict litigation (MDL) in the Eastern Pennsylvania District Court, and the plaintiff in the Local 1500 lawsuit filed a motion seeking to have the four lawsuits, along with *Cipla Ltd. v. Amgen Inc.*, consolidated and designated as a MDL in the Delaware District Court. On July 31, 2019, the MDL panel entered an order consolidating in the Delaware District Court the four class action lawsuits. On September 13, 2019, the plaintiffs filed amended complaints, and on October 15, 2019, Amgen filed its motion to dismiss both the direct purchaser plaintiffs' consolidated class action complaint and the indirect purchaser end payor plaintiffs' complaint. On December 6, 2019, the plaintiffs responded to Amgen's motion to dismiss and, on January 10, 2020, Amgen filed its response.

On February 6, 2020, an additional class action lawsuit was filed by MSP Recovery Claims against Amgen, Teva, Watson and Actavis also alleging anticompetitive conduct in connection with settlements between Amgen and manufacturers of generic cinacalcet product. This action was brought in the U.S. District Court for the Southern District of Florida, captioned *MSP Recovery Claims v. Amgen Inc., et al.*

Humira® Biosimilar Antitrust Class Actions

From March 18, 2019, to May 10, 2019, twelve purported class actions against Amgen, along with AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively, AbbVie), were filed in the U.S. District Court for the Northern District of Illinois (the Illinois Northern District Court). The cases are captioned: *UFCW Local 1500 Welfare Fund v. AbbVie Inc., et al.* (March 18, 2019) (Local 1500); *Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund v. AbbVie Inc., et al.* (March 20, 2019); *Mayor and City Council of Baltimore v. AbbVie Inc., et al.* (March 22, 2019); *Pipe Trades Services MN Welfare Fund v. AbbVie Inc., et al.* (March 29, 2019); *St. Paul Electrical Workers' Health Plan v. AbbVie Inc., et al.* (March 29, 2019); *Welfare Plan of the International Union of Operating Engineers Locals 137, 137A, 137B, 137C and 137R v. AbbVie Inc., et al.* (April 1, 2019); *Law Enforcement Health Benefits, Inc. v. AbbVie, Inc., et al.* (April 9, 2019) (Law Enforcement); *Kentucky Laborers District Council Health and Welfare Fund v. AbbVie, Inc., et al.* (April 16, 2019); *Sheet Metal Workers' Local Union No. 28 Welfare Fund v. AbbVie, Inc., et al.* (April 19, 2019) (Sheet Metal Workers'); *Locals 302 & 612 of The International Union of Operating Engineers-Employers Construction Industry Health And Security Trust Fund v. AbbVie Inc., et al.* (April 25, 2019) (Construction Industry); *Louisiana Health Service & Indemnity Co., d/b/a Blue Cross and Blue Shield of Louisiana and HMO Louisiana, Inc. v. AbbVie Inc., et al.* (April 30, 2019) (Louisiana Health); and *Cleveland Bakers and Teamsters Health and Welfare Fund v. AbbVie Inc., et al.* (May 10, 2019) (Cleveland Bakers) collectively, Humira® Antitrust Class Actions).

In each of the Humira® Antitrust Class Actions, the plaintiffs bring federal antitrust claims along with various state law claims under common law and antitrust, consumer protection and unfair competition statutes. In each case, the plaintiffs specifically allege that AbbVie has unlawfully monopolized the alleged market for Humira® and biosimilars of Humira®, including by creating an allegedly unlawful so-called patent thicket around Humira®. In the Local 1500, Sheet Metal Workers' and Construction Industry cases, the plaintiffs further allege that AbbVie entered into allegedly unlawful market division agreements with Amgen and other companies that had developed Humira® biosimilars, including Bioepis, Mylan, Sandoz, Inc., Fresenius Kabi USA, LLC, Pfizer Inc. and Momenta Pharmaceuticals, Inc., in connection with the settlement of patent litigation relating to Humira®, whereby Amgen and the other defendants that have developed Humira® biosimilars were permitted to market those products in Europe as

early as October 2018, while remaining off the market in the United States until 2023. In each of the Humira® Antitrust Class Actions other than the Local 1500 and Construction Industry cases, the plaintiffs allege that AbbVie and Amgen entered into an allegedly unlawful settlement agreement under which Amgen allegedly agreed to delay its entry into the U.S. market with AMGEVITA™, its Humira® biosimilar, in exchange for an alleged promise of exclusivity as the sole Humira® biosimilar in that market for five months, beginning in January 2023. In each of the Humira® Antitrust Class Actions, plaintiffs seek injunctive relief, treble damages

and attorney's fees on behalf of a putative class of third-party payers and/or consumers that have indirectly purchased, paid for or provided reimbursement for Humira® in the United States. Defendants' responses to the first six complaints were stayed by the court. On June 4, 2019, the Illinois Northern District Court entered an order consolidating the twelve purported class action cases for pre-trial purposes and on June 13, 2019, entered an order requiring the plaintiffs to file a consolidated complaint by August 12, 2019. On August 9, 2019, the plaintiffs filed their consolidated complaint in the Illinois Northern District Court. The consolidated class action complaint names as defendants Amgen, along with AbbVie, Bioepis, Sandoz, Inc. and Fresenius Kabi USA LLC. On October 11, 2019, the defendants filed a joint motion to dismiss the consolidated complaint (as well as brief individual motions), challenging the legal sufficiency of the plaintiffs' allegations to state any claim for relief under the law. On November 19, 2019, plaintiffs filed their opposition to the motion to dismiss. On December 20, 2019, defendants filed their reply in support of the motion to dismiss. No argument date has been set.

Commitments – U.S. repatriation tax

Under the 2017 Tax Act, we elected to pay in eight annual installments the repatriation tax related primarily to prior indefinitely invested earnings of our foreign operations. See Note 6, Income taxes. The following table summarizes the remaining scheduled repatriation tax payments as of December 31, 2019 (in millions):

	Amounts
2020	$ 587
2021	587
2022	587
2023	1,100
2024	1,467
Thereafter	1,834
Total remaining U.S. repatriation tax commitments	$ 6,162

20. Quarterly financial data (unaudited)

The following tables summarize the Company's unaudited financial data on a quarterly basis. The sum of the quarterly earnings per-share amounts may not equal the amount reported for the full year because per-share amounts are computed independently for each quarter and for the full year based on respective weighted-average shares outstanding and dilutive securities.

Quarterly financial data is summarized as follows (in millions, except per-share data):

	2019 Quarters ended			
	December 31	September 30	June 30	March 31
Product sales	$ 5,881	$ 5,463	$ 5,574	$ 5,286
Gross profit from product sales	$ 4,628	$ 4,427	$ 4,562	$ 4,231
Net income	$ 1,703	$ 1,968	$ 2,179	$ 1,992
Earnings per share:				
Basic	$ 2.87	$ 3.29	$ 3.59	$ 3.20
Diluted	$ 2.85	$ 3.27	$ 3.57	$ 3.18
	2018 Quarters ended			
	December 31	**September 30**	**June 30**	**March 31**
Product sales	$ 6,001	$ 5,510	$ 5,679	$ 5,343
Gross profit from product sales	$ 4,905	$ 4,473	$ 4,655	$ 4,399
Net income	$ 1,928	$ 1,859	$ 2,296	$ 2,311
Earnings per share:				
Basic	$ 3.04	$ 2.88	$ 3.50	$ 3.27
Diluted	$ 3.01	$ 2.86	$ 3.48	$ 3.25

21. Subsequent events

On January 2, 2020, Amgen acquired a 20.5% stake in BeiGene, Ltd. (BeiGene) for approximately $2.8 billion in cash as part of a collaboration to expand our oncology presence in China. We will account for this investment by using the equity method. Under the collaboration, BeiGene will commercialize XGEVA®, KYPROLIS® and BLINCYTO® (blinatumomab) in China, and we will share profits and losses equally during the initial product-specific commercialization periods; thereafter, two of these products will revert to Amgen, and Amgen will pay royalties to BeiGene on sales in China of such products for a specified period.

In addition, Amgen and BeiGene will jointly develop 20 of our oncology product candidates, with BeiGene sharing in global R&D costs of up to $1.25 billion and assuming commercialization rights in China for a specified period. Amgen and BeiGene will share profits in China equally until certain of these product rights revert to Amgen. After reversion, Amgen will pay royalties to BeiGene on sales in China for a specified period. For product sales outside of China, Amgen will pay BeiGene royalties.

SCHEDULE II

AMGEN INC.

VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2019, 2018 and 2017

(In millions)

Allowance for doubtful accounts	Balance at beginning of period	Additions charged to costs and expenses	Other additions	Deductions	Balance at end of period
Year ended December 31, 2019	$ 48	$ —	$ —	$ 22	$ 26
Year ended December 31, 2018	$ 51	$ 1	$ —	$ 4	$ 48
Year ended December 31, 2017	$ 51	$ 4	$ —	$ 4	$ 51

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**95-3540776**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive, Thousand Oaks, California	**91320-1799**
(Address of principal executive offices)	(Zip Code)

(805) 447-1000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common stock, $0.0001 par value	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company	Emerging growth company
☒	☐	☐	☐	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $119,629,312,769 as of June 30, 2018.[(A)]

(A) Excludes 884,143 shares of common stock held by directors and executive officers, and any stockholders whose ownership exceeds ten percent of the shares outstanding, at June 30, 2018. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

622,278,034

(Number of shares of common stock outstanding as of February 7, 2019)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2019 Annual Meeting of Stockholders to be held May 21, 2019, are incorporated by reference into Part III of this annual report.

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PART I

Item 1. BUSINESS

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen was incorporated in California in 1980 and became a Delaware corporation in 1987. We have a presence in approximately 100 countries worldwide. Amgen operates in one business segment: human therapeutics.

Significant Developments

Following is a summary of significant developments affecting our business that have occurred and that we have reported since the filing of our Annual Report on Form 10-K for the year ended December 31, 2017, and in early 2018.

Products/Pipeline

Oncology/Hematology

BLINCYTO® (blinatumomab)

- In March 2018, we announced that the U.S. Food and Drug Administration (FDA) approved under accelerated approval the supplemental Biologics License Application (sBLA) for BLINCYTO® for the treatment of adults and children with B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease greater than or equal to 0.1 percent.

- In June 2018, we announced that the European Commission (EC) granted a full marketing authorization for BLINCYTO® based on the overall survival data from the phase 3 TOWER study in adult patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL.

- In August 2018, we announced that the EC approved an expanded indication for BLINCYTO® as monotherapy for the treatment of pediatric patients aged one year or older with Philadelphia chromosome-negative CD19 positive B-cell precursor ALL, which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation.

- In January 2019, we announced that the EC approved an expanded indication for BLINCYTO® as monotherapy to include adult patients with Philadelphia chromosome-negative CD19 positive B-cell precursor ALL in first or second complete remission with minimal residual disease greater than or equal to 0.1 percent.

KYPROLIS® (carfilzomib)

- In January 2018, we announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion resulting in a label variation for KYPROLIS® to include updated overall survival data from the phase 3 head-to-head ENDEAVOR (RandomizEd, OpeN Label, Phase 3 Study of Carfilzomib Plus DExamethAsone Vs Bortezomib Plus DexamethasOne in Patients With Relapsed Multiple Myeloma) study in patients with relapsed or refractory multiple myeloma.

- In April 2018, we announced that the CHMP of the EMA adopted a positive opinion resulting in a label variation for KYPROLIS® to include the final overall survival data from the phase 3 ASPIRE (CArfilzomib, Lenalidomide, and DexamethaSone versus Lenalidomide and Dexamethasone for the

treatment of PatIents with Relapsed Multiple MyEloma) study. In June 2018, we announced that the FDA approved the supplemental New Drug Application (sNDA) to add the positive overall survival data from the ASPIRE study to the U.S. Prescribing Information for patients with relapsed or refractory myeloma.

- In October 2018, we announced that the FDA approved the sNDA to expand the Prescribing Information for KYPROLIS® to include a once-weekly dosing option in combination with dexamethasone for patients with relapsed or refractory multiple myeloma.

Neulasta® (pegfilgrastim)

- In February 2018, we announced that the CHMP of the EMA issued a positive opinion recommending a label variation for Neulasta® to include the Neulasta® Onpro® kit.

Cardiovascular

Repatha® (evolocumab)

- In May 2018, we announced that the EC approved a new indication in the Repatha® label for adults with established atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral arterial disease) to reduce cardiovascular risk by lowering low-density lipoprotein (LDL) cholesterol levels.

- In October 2018, we announced a set of new National Drug Codes (NDCs) to make Repatha® available at a 60% lower list price of $5,850 per year to address affordability for patients, particularly those on Medicare.

- In January 2019, we announced that the National Medical Products Administration approved a new indication for Repatha® as the first PCSK9 inhibitor in China for adults with established atherosclerotic cardiovascular disease to reduce the risk of myocardial infarction, stroke and coronary revascularization.

Neuroscience

Aimovig® (erenumab-aooe)

- In May 2018, we announced that the FDA approved Aimovig® for the preventive treatment of migraine in adults. Aimovig® is part of a joint development and commercialization collaboration with Novartis AG (Novartis).

Inflammation

Tezepelumab

- In September 2018, we announced that the FDA granted Breakthrough Therapy Designation for tezepelumab in patients with severe asthma without an eosinophilic phenotype. Tezepelumab is being developed jointly in collaboration with AstraZeneca plc (AstraZeneca).

Bone health

EVENITY™ (romosozumab)*

- In January 2019, we and UCB, our global collaboration partner in the development of EVENITY™, announced that the FDA Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) voted to recommend approval of EVENITY™ for the treatment of osteoporosis in postmenopausal women at high risk for fracture. Also in January 2019, the Japanese Ministry of Health, Labor and Welfare granted a marketing authorization for the treatment of osteoporosis in men and postmenopausal women at high risk of fracture.

Prolia® (denosumab)

- In May 2018 and June 2018, the FDA and the EC, respectively, approved a new indication for Prolia® for the treatment of glucocorticoid-induced osteoporosis in adult patients at high risk of fracture.

XGEVA® (denosumab)

-

In April 2018, we announced that the EC approved an expanded indication for XGEVA® for the prevention of skeletal-related events (SREs) in patients with multiple myeloma.

Biosimilars

AMGEVITA™ (biosimilar adalimumab)

- In October 2018, we began launching AMGEVITA™ in markets across Europe.

KANJINTI™ (biosimilar trastuzumab / formerly ABP 980)*

- In May 2018, the EC granted marketing authorization for KANJINTI™, a biosimilar candidate to Herceptin®, for the treatment of HER2-positive metastatic breast cancer, HER2-positive early breast cancer and HER2-positive metastatic adenocarcinoma of the stomach or gastroesophageal junction. KANJINTI™ is being developed in collaboration with Allergan plc (Allergan).

- In May 2018, we announced that we received a Complete Response Letter from the FDA for the Biologics License Application (BLA) for KANJINTI™. In December 2018, we refiled our BLA with the FDA for KANJINTI™.

ABP 710 (biosimilar infliximab)

- In June 2018, we announced results from a phase 3 study evaluating the efficacy and safety of biosimilar candidate ABP 710 compared with REMICADE® (infliximab) in patients with moderate-to-severe rheumatoid arthritis. The results confirmed noninferiority compared to infliximab but could not rule out superiority based on its primary efficacy endpoint.

- In December 2018 and January 2019, we submitted a BLA to the FDA and a Marketing Authorization Application (MAA) to the EMA, respectively, for ABP 710.

ABP 798 (biosimilar rituximab)

- In January 2019, we and Allergan announced positive top-line results from a phase 1/phase 3 study evaluating the pharmacokinetics, efficacy and safety of ABP 798, a biosimilar candidate to RITUXAN® (rituximab), compared to rituximab in patients with moderate-to-severe rheumatoid arthritis. The results demonstrate that the study met its primary endpoint of pharmacokinetic similarity. Additionally, equivalent efficacy was established and a similar safety profile was demonstrated.

Next-generation biomanufacturing

- In April 2018, we announced plans to build a new next-generation biomanufacturing plant on our campus in West Greenwich, Rhode Island. The new plant will employ our next-generation biomanufacturing capabilities and manufacture products for the U.S. and global markets.

* FDA provisionally approved trade name.

Marketing, Distribution and Selected Marketed Products

The largest concentration of our sales and marketing forces is based in the United States and Europe. Additionally, we continue to expand the commercialization and marketing of our products into other geographic territories, including parts of Latin America, the Middle East and Asia. This expansion is occurring by establishing our own affiliates, by acquiring existing third-party businesses or product rights or by partnering with third parties. Whether we use our own sales and marketing forces or a third party's varies across these markets. Such use typically depends on several factors, including the nature of entry into the new market, the size of an opportunity and operational capabilities. Together with our partners, we market our products to healthcare providers, including physicians or their clinics, dialysis centers, hospitals and pharmacies.

In the United States, we sell primarily to pharmaceutical wholesale distributors, which are the principal means of distributing our products to healthcare providers. We also market certain products through direct-to-consumer channels including, print, television and online media. For further discussion, see Government Regulation—Regulation in the United States—Regulation of Product Marketing and Promotion. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country.

Our product sales to three large wholesalers, AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc., each individually accounted for more than 10% of total revenues for each of the years ended December 31, 2018, 2017 and 2016. On a combined basis, these wholesalers accounted for 98%, 96% and 96% of our U.S. gross product sales for each of the years ended December 31, 2018, 2017 and 2016, respectively, and 84%, 81% and 81% of worldwide gross revenues for each of these years. We monitor the financial condition of our larger

customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

Our products are marketed around the world, with the United States being our largest market. The following chart shows our product sales by principal product and by geography for the years ended 2018, 2017 and 2016.

a2018productsalesgrapha10.jpg

Enbrel® (etanercept)

We market ENBREL primarily in the United States. It was launched in 1998 and is used primarily in indications for the treatment of adult patients with the following conditions:

- moderately to severely active rheumatoid arthritis;
- chronic moderate-to-severe plaque psoriasis patients who are candidates for systemic therapy or phototherapy; and
- active psoriatic arthritis.

Neulasta® (pegfilgrastim)

We market Neulasta®, a pegylated protein based on the filgrastim molecule, primarily in the United States and Europe. Neulasta® was launched in 2002 and is used primarily in the indication to help reduce the chance of infection due to a low white blood cell count, in patients with certain types of cancer (nonmyeloid) who receive anticancer medicines (chemotherapy) that can cause fever and a low blood cell count. In 2015, the Neulasta® Onpro® kit became available in the United States. The Neulasta® Onpro® kit provides physicians the opportunity to initiate the administration of Neulasta® on the same day as chemotherapy, with drug delivery of the recommended dose of Neulasta® at home the day after chemotherapy, thereby saving patients a trip back to the doctor.

Prolia® (denosumab)

We market Prolia® primarily in the United States and Europe. Prolia® contains the same active ingredient as XGEVA® (denosumab) but is approved for different indications, patient populations, doses and frequencies of administration. Prolia® was launched in the United States and Europe in 2010. In the United States, it is used primarily in the indication for the treatment of postmenopausal women with osteoporosis at high risk of fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In Europe, Prolia® is used primarily for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Aranesp® (darbepoetin alfa)

We market Aranesp® primarily in the United States and Europe. It was launched in 2001 and is indicated to treat a lower-than-normal number of red blood cells (anemia) caused by chronic kidney disease (CKD) (in both patients on dialysis and patients not on dialysis). Aranesp® is also indicated for the treatment of anemia due to concomitant myelosuppressive chemotherapy in certain patients with nonmyeloid malignancies and when chemotherapy will be used for at least two months after starting Aranesp®.

Aranesp® and EPOGEN® (epoetin alfa) compete with each other in the United States, primarily in the dialysis setting.

XGEVA®

We market XGEVA® primarily in the United States and Europe. XGEVA® was launched in the United States in 2010 and is now used primarily in the indication for the prevention of SREs (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumors and multiple myeloma. XGEVA® was launched in Europe in 2011 and is used primarily in the indication for the prevention of SREs in patients with bone metastases from solid tumors. It was approved in January 2018 in the United States and April 2018 in Europe for the prevention of SREs in patients with multiple myeloma.

Sensipar®/Mimpara® (cinacalcet)

We market cinacalcet as Sensipar® primarily in the United States and as Mimpara® primarily in Europe. It was launched in 2004 and is used primarily in the indication for the treatment of secondary hyperparathyroidism in adult patients with CKD who are on dialysis.

Sensipar® and our recently launched Parsabiv® (etelcalcetide) compete with each other.

EPOGEN®

We market EPOGEN® in the United States for dialysis patients. EPOGEN® was launched in 1989, and we market it for the indication to treat anemia caused by CKD in patients on dialysis in order to lessen the need for red blood cell transfusions. The majority of our sales are to a large dialysis provider.

Other Marketed Products

We also market a number of other products in various markets worldwide, including KYPROLIS® (carfilzomib), Nplate® (romiplostim), Vectibix® (panitumumab), Repatha® (evolocumab), NEUPOGEN® (filgrastim), Parsabiv®, BLINCYTO® (blinatumomab), Aimovig® (erenumab-aooe), IMLYGIC® (talimogene laherparepvec), Corlanor® (ivabradine), KANJINTI™ (biosimilar trastuzumab) and AMGEVITA™ (biosimilar adalimumab).

Patents

The following table lists our outstanding material patents for the indicated product by territory, general subject matter and latest expiry date. Certain of the European patents are the subjects of supplemental protection certificates that provide additional protection for the products in certain European countries beyond the dates listed in the table (see footnotes).

One or more patents with the same or earlier expiry date may fall under the same general subject matter and are not listed separately.

Product	Territory	General subject matter	Expiration
Enbrel® (etanercept)	U.S.	Methods of treating psoriasis	8/13/2019
	U.S.	Aqueous formulation and methods of treatment using the formulation	6/8/2023
	U.S.	Fusion protein, and pharmaceutical compositions	11/22/2028
	U.S.	DNA encoding fusion protein, and methods of making fusion protein	4/24/2029
Prolia®/ XGEVA® (denosumab)	U.S.	RANKL antibodies	9/17/2021
	U.S.	Methods of treatment	6/25/2022
	U.S.	Nucleic acids encoding RANKL antibodies, and methods of producing RANKL antibodies	11/30/2023
	U.S.	RANKL antibodies including sequences	2/19/2025
	Europe	RANKL antibodies including epitope binding	2/23/2021
	Europe	RANKL antibodies including sequences(1)	6/25/2022
Aranesp® (darbepoetin alfa)	U.S.	Glycosylation analogs of erythropoietin proteins	5/15/2024
Sensipar®/ Mimpara® (cinacalcet)	U.S.	Formulation	9/22/2026
	Europe	Calcium receptor-active molecules(1)	10/23/2015
	Europe	Formulation	9/10/2024
KYPROLIS® (carfilzomib)	U.S.	Compositions and compounds	12/7/2027
	U.S.	Methods of treatment	4/14/2025
	U.S.	Methods of making	5/8/2033
	Europe	Compositions, compounds and methods of treatment(1)	8/8/2025
Nplate® (romiplostim)	U.S.	Thrombopoietic compounds	1/19/2022
	U.S.	Formulation	2/12/2028
	Europe	Thrombopoietic compounds(1)	10/22/2019
	Europe	Formulation	4/20/2027
Vectibix® (panitumumab)	U.S.	Human monoclonal antibodies to epidermal growth factor receptor	4/8/2020
	Europe	Human monoclonal antibodies to epidermal growth factor receptor(1)	5/5/2018
Repatha® (evolocumab)	U.S.	Antibodies(2)	10/25/2029
	U.S.	Methods of treatment	10/8/2030
	Europe	Compositions and method of treatment	8/22/2028
Parsabiv® (etelcalcetide)	U.S.	Compound and pharmaceutical composition(2)	7/29/2030
	U.S.	Formulation	6/27/2034
	Europe	Compound and pharmaceutical composition	7/29/2030
	Europe	Formulation	6/27/2034
BLINCYTO® (blinatumomab)	U.S.	Bifunctional polypeptides(2)	4/21/2019
	U.S.	Method of administration	9/28/2027
	Europe	Bifunctional polypeptides(1)	11/26/2024
	Europe	Method of administration	11/29/2026
Aimovig® (erenumab-aooe)	U.S.	CGRP receptor antibodies(2)	11/9/2031
	U.S.	Methods of treatment	12/18/2029
	Europe	CGRP receptor antibodies and methods of treatment	12/18/2029
IMLYGIC® (talimogene laherparepvec)	U.S.	Compositions	11/23/2025
	U.S.	Method of treatment	3/27/2022
	Europe	Composition and uses(1)	3/27/2022

Corlanor® (ivabradine)	U.S.	Crystalline forms	2/22/2026

(1) A European patent with this subject matter may also be entitled to supplemental protection in one or more countries in Europe, and the length of any such extension will vary by country. For example, supplementary protection certificates have been issued related to the indicated products for patents in at least the following countries:

- denosumab — France, Italy, Spain and the United Kingdom, expiring in 2025
- cinacalcet — Germany expiring in 2019; France, Italy, Spain and the United Kingdom, expiring in 2020
- carfilzomib — France, Germany, Italy and Spain, expiring in 2030
- romiplostim — France, Germany, Italy, Spain and the United Kingdom, expiring in 2024
- panitumumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2022
- evolocumab — France and Spain, expiring in 2030
- blinatumomab — France, Italy and Spain, expiring in 2029
- erenumab — Italy expiring in 2033
- talimogene laherparepvec — Spain, expiring in 2026; France, Germany, Italy and the United Kingdom, expiring in 2027

(2) A patent with this subject matter may be entitled to patent term extension in the United States.

Competition

We operate in a highly competitive environment. A number of our marketed products are indicated in disease areas in which other products or treatments are currently available or are being pursued by our competitors through research and development (R&D) activities. Additionally, some competitor-marketed products target the same genetic pathways as our recently launched marketed products or are being pursued currently. This competition could impact the pricing and market share of our products. We continue to pursue ways to increase the value of our medicines through innovations during their life cycles, which can include expanding the disease areas for which our products are indicated and finding new methods to make the delivery of our medicines easier and less costly. Such activities can offer important opportunities for differentiation. For example, in 2015, we launched the Neulasta® Onpro® kit, which provides physicians the opportunity to initiate the administration of the recommended dose of Neulasta® on the same day as chemotherapy, with drug delivery at home the day after chemotherapy, thereby saving patients a trip back to the doctor. We also launched in 2017 the AutoTouch® reusable auto-injector to be used with Enbrel Mini® single-dose prefilled cartridges (50 mg/mL). The Enbrel Mini® utilizes a new drug formulation of ENBREL that was associated with statistically significant lower mean injection site pain than the current formulation. We plan to continue pursuing innovation efforts to strengthen our competitive position. Such position may be based on, among other things, safety, efficacy, reliability, availability, patient convenience/delivery devices, price, reimbursement, access to and timing of market entry and patent position and expiration.

Certain of the existing patents on our principal products have expired, and we face new and increasing competition, including from biosimilars and generics. We may also compete against biosimilar or generic versions of our competitors' products. A biosimilar is another version of a biological product for which marketing approval is sought or has been obtained based on a demonstration that it is "highly similar" to the original reference product. We expect that the adverse impact on our product sales from biosimilar competition will be more like branded biologic competition than that seen when branded small molecules face generics, but we believe that when multiple biosimilar versions of one of our products get approved and launched, competition could intensify more rapidly, resulting in a greater impact on our product's sales. Although we expect biosimilars to compete on price, we believe many patients, providers and payers will continue to place high value on the reputation, reliability and safety of our products. In the United States, companies now have approved biosimilar versions of EPOGEN®, NEUPOGEN®, Neulasta® and ENBREL. See also Government Regulation—Regulation in the United States—Approval of Biosimilars. As biosimilar competitors come to market, we will leverage both the experience we have had in the United States versus branded competition and our experience in competing against epoetin alfa and filgrastim biosimilars in Europe. In addition, although most of our products are biologics, some of our products are small-molecule products. Because the FDA approval process allows generic manufacturers to rely on the safety and efficacy data of the innovator product rather than having to conduct their own costly and time-consuming clinical trials, generic manufacturers can often market their competing versions of our small-molecule products at much lower prices. As a result, upon the expiration or loss of patent protection for a small-molecule product, we can lose the majority of revenues for that product in a very short period of time.

The introduction of new products, the development of new processes or technologies by competitors or the emergence of new information about existing products may result in increased competition for our marketed products, even for those protected by patents, or in reductions in the prices we receive from selling our products. In addition, the development of new treatment options or standards of care may reduce the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates. (As used in this document, the term *clinical trials* may include prospective clinical trials, observational studies, registries and other studies.) See Item 1A. Risk Factors—*Our products face substantial competition* and Item 1A. Risk Factors—*We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future.*

The following table reflects our significant competitors and is not exhaustive.

Product	Territory	Competitor-marketed product	Competitors
ENBREL	U.S. & Canada	REMICADE®*	Janssen Biotech, Inc. (Janssen)(1)
	U.S. & Canada	HUMIRA®	AbbVie Inc.
	U.S. & Canada	STELARA®(2)	Janssen(1)
	U.S. & Canada	Otezla®(2)	Celgene Corporation (Celgene)
Neulasta®(3)	U.S.	UDENYCA™	Coherus BioSciences, Inc.
	U.S.	Fulphila®	Mylan Institutional Inc.
	U.S. & Europe	Filgrastim biosimilars	Various
Prolia®	U.S. & Europe	Alendronate, raloxifene and zoledronate generics	Various
Aranesp®	U.S.	PROCRIT®(4)	Janssen(1)
	U.S.	MIRCERA®(5)	Galenica Group (Galenica)/F. Hoffmann-La Roche Ltd. (Roche)
	U.S. & Europe	Epoetin alfa biosimilars	Various
XGEVA®	U.S. & Europe	Zoledronate generics	Various
Sensipar®(6)/ Mimpara®	U.S. & Europe	Active vitamin D analogs	Various
EPOGEN®(3)	U.S.	MIRCERA®(5)	Galenica/Roche
	U.S.	RETACRIT™	Hospira(7)
KYPROLIS®(9)	U.S.	VELCADE®	Millennium Pharmaceuticals, Inc.(8)
	U.S.	REVLIMID®	Celgene
	U.S.	POMALYST®	Celgene
	U.S.	DARZALEX®	Janssen(1)
Repatha®	U.S. & Europe	PRALUENT®	Regeneron Sanofi
Parsabiv®	U.S. & Europe	Active vitamin D analogs	Various
Aimovig®	U.S.	AJOVY™	Teva Pharmaceuticals USA, Inc.
	U.S.	Emgality™	Eli Lilly and Company

* Approved biosimilars available.

(1) A subsidiary of Johnson & Johnson (J&J).

(2) Dermatology only.

(3) Other biosimilars under regulatory review in the United States and Europe.

(4) PROCRIT® competes with Aranesp® in the supportive cancer care and predialysis settings.

(5) MIRCERA® competes with Aranesp® only in the nephrology segment.

(6) Our U.S. composition of matter patent for Sensipar® expired in March 2018. We are engaged in litigation with a number of companies seeking to market generic versions of Sensipar® surrounding our U.S. formulation patent that expires in September 2026. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements, for further information. Several of these generic versions of Sensipar® have been approved by the FDA.

(7) A subsidiary of Pfizer Inc. (Pfizer)

(8) A subsidiary of Takeda Pharmaceutical Company Limited.

(9) KYPROLIS® is facing increased competition from several recently approved products.

Reimbursement

Sales of our principal products are dependent on the availability and extent of coverage and reimbursement from third-party payers. In many markets around the world, these payers, including government health systems, private health insurers and other organizations, remain focused on reducing the cost of healthcare, and their efforts have intensified as a result of rising healthcare costs and economic challenges. Drugs, and in particular specialty drugs such as our products, remain heavily scrutinized for cost containment. As a result, payers are becoming more restrictive regarding the use of biopharmaceutical products and scrutinizing the prices of these products, while requiring a higher level of clinical evidence to support the benefit such products bring to patients and the broader healthcare system. These pressures are intensified where our products are subject to increasing competition.

In the United States, healthcare providers and other entities such as pharmacies and Pharmacy Benefit Managers (PBMs) are reimbursed for covered services and products they deliver through Medicare, Medicaid and other government healthcare programs, as well as through private payers. We are required to provide rebates or discounts on our products that are reimbursed through certain government programs, including Medicare and Medicaid, and also provide discounts to qualifying healthcare providers under the Federal 340B Drug Pricing Program. In addition, we provide rebates to PBMs, as well as other entities (such as hospitals and pharmacies), which are payments by a biopharmaceutical manufacturer of a portion of the product's purchase price back to the PBMs or other entities.

Biopharmaceutical-product pricing remains central to discussions on controlling healthcare costs in the United States. Policy makers from both of the major U.S. political parties are pursuing policies to lower drug costs for patients. In May 2018, U.S. president Donald Trump and his administration released a drug-pricing "blueprint" and requested public comment on an array of policy ideas intended to increase competition, improve the federal government's negotiating power, reduce drug prices and lower patients' out-of-pocket costs. The blueprint included a number of policy ideas with the potential to significantly affect, whether individually or collectively, the biopharmaceutical industry; and the U.S. presidential administration has already begun to implement certain elements described in the administration's drug-pricing blueprint, such as (i) seeking initial feedback on a potential program that would set the Medicare payment amount for Part B single-source drugs and biologics to be more closely aligned with international drug prices and rely on third-party vendors, (ii) issuing guidance to allow certain Medicare plans offered by private insurance companies to begin requiring that patients receiving Medicare Part B drugs first try a drug preferred by the plan before such plan will cover another therapy, (iii) lowering initial reimbursement rates for new Part B drugs launched beginning in 2019 and (iv) proposing new rules to require drug price information in direct-to-consumer drug television advertising. The blueprint also discussed (i) the potential removal of the safe-harbor protection under the federal anti-kickback statute for drug rebates paid to payers and (ii) changes to the Part D program. At the same time, value assessments of new technologies previously used predominantly outside the United States are having an impact in the U.S. healthcare environment. Healthcare provider organizations and independent organizations are creating their own value assessments of biopharmaceutical drugs for comparison with manufacturer pricing. Although these organizations do not set drug prices, they seek to influence pricing as well as payer and provider decision making by publicly disclosing their assessments, often making assertions around what they believe to be the appropriate price to charge for a product. In addition, continued consolidation of payers and integration of providers and payers (integrated delivery systems) increase the level of market power held by our customers. Such developments, particularly when taken in combination with increasing product competition, put greater pressure on access to, pricing of and sales of our products.

In addition, rebates and/or discount levels as well as the number of entities that are entitled to receive them since they are reimbursed through government programs have increased over time. For example, the Bipartisan Budget Act, enacted in 2018, requires biopharmaceutical manufacturers to pay greater discounts for patients in the Medicare Part D coverage gap beginning in 2019; and the Patient Protection and Affordable Care Act (ACA), enacted in 2010, increased many of the mandatory discounts and rebates required of us. The ACA also imposed a new Branded Prescription Pharmaceutical Manufacturers and Importers fee payable each year by us and other manufacturers. In the Tax Cuts and Jobs Act (2017 Tax Act) signed by President Trump in December 2017, Congress removed a key ACA provision by repealing the individual mandate penalty, which required every person to have health insurance or pay a penalty. Future changes to government programs such as the ACA, whether legislative or regulatory, could impact the number of patient lives covered, could raise or lower the cost or quality of insurance, could affect Medicaid eligibility and could change levels of patient protections provided unless alternatives are put in place.

Other government legislative and regulatory actions that would have a significant impact on Amgen include changes to how the Medicare program covers and reimburses current and future drugs, including for patients with

end-stage renal disease (ESRD); changes in the federal payment rate or new rebate requirements for covered drugs and policies for drug payment in Medicare or Medicaid; and changes to coverage and payment for biosimilars, such as policies that would facilitate easier substitution for, or provide reimbursement advantages over, the corresponding innovative products. In ESRD, the Centers for Medicare & Medicaid Services (CMS) uses a bundled-payment system and recently finalized changes allowing more new dialysis drugs to be eligible for temporary add-on payment adjustments starting in 2020. Sensipar® and Parsabiv® were already eligible for add-on payment adjustments beginning in 2018 and will continue to receive them in 2019. CMS has indicated interest in testing new models for drug payment in Medicare Part B and Part D. CMS also continues to test alternative payment models with providers, such as the

Oncology Care Model. These models provide financial incentives for providers who participate; under the models, providers take on greater risk for the overall cost and quality of care. In addition, in 2018 CMS implemented changes to Medicare payment to hospitals for Part B drugs acquired through the Federal 340B Drug Pricing Program but provided a financial incentive for hospitals to use biosimilar products over the corresponding innovative products. As described above, CMS is permitting Medicare Advantage plans to implement access controls for Part B drugs while also (i) considering a proposal that would set the Medicare payment amount for Part B single-source drugs and biologics to more closely align with international drug prices and rely on third-party vendors and (ii) considering changes to Medicare Part D and Medicare Advantage. These and/or other changes have the potential to impact prescribing and patient access to Amgen's therapies.

Additional efforts by state legislatures and government agencies in the United States could also affect us and our industry. For example, a California law requires manufacturers to provide payers advance notice of a price increase over a specified threshold, and laws in Oregon and Vermont require manufacturers to submit price increase justifications to a state attorney agency if certain price increase and state-spending thresholds are met. Examples of other proposals that have been discussed and debated but not yet enacted include state ballot initiatives that would place a maximum price ceiling, or cap, on pharmaceutical products purchased by state agencies and state legislative efforts to cap pharmaceutical prices for commercial payers.

In the U.S. private sector, payers continue to institute cost reduction and containment measures that lower drug utilization and/or spending altogether and/or shift a greater portion of the costs to patients. Such measures include more limited benefit plan designs, higher patient co-pays or coinsurance obligations, limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs), stricter utilization management criteria before a patient may get access to a drug, and/or higher-tier formulary placement that increases the level of patient out-of-pocket costs. The use of such measures by PBMs and insurers that handle the majority of sales for ENBREL and Repatha® has continued to intensify and thereby limited Amgen product usage and sales. Consolidation has resulted in a smaller number of PBMs and insurers overseeing a large portion of total covered lives in the United States. As a result, PBMs and insurers have greater market power and negotiating leverage to mandate stricter utilization criteria and/or exclude drugs from their formularies in favor of competitor drugs or alternative treatments. Our past experience with Repatha® underscores that utilization management requirements, including the burdensome administrative processes required of physicians to demonstrate and document that patients meet such requirements, continue to be a significant challenge for patients and physicians, limiting access for appropriate usage. Formulary exclusion effectively encourages patients and providers to seek alternative treatments or pay 100% of the cost of a drug. A drug's inclusion and favorable positioning on formulary is essential to ensure patients have access. Even when access is available, some patients abandon their prescriptions due to economic reasons. In highly competitive treatment markets such as with ENBREL, Repatha® and Aimovig®, PBMs are also able to exert negotiating leverage by requiring incremental rebates from manufacturers in order to maintain their formulary position.

In many countries outside the United States, government-sponsored healthcare systems are the primary payers for drugs and biologics. With increasing budgetary constraints, and/or difficulty in understanding the value of medicines, governments and payers in many countries are applying a variety of measures to exert downward price pressure. These measures can include mandatory price controls; price referencing; therapeutic-reference pricing; increases in mandates; incentives for generic substitution and biosimilar usage; and government-mandated price cuts. In this regard, many countries have health technology assessment organizations that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies, and these organizations are expanding in established and emerging markets. We expect that countries will continue to take aggressive actions to seek to reduce expenditures on drugs and biologics. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

The dynamics and developments discussed above serve to create pressure on the pricing and potential usage of our products and the industry. We remain focused on delivering breakthrough treatments for unmet medical needs. Amgen is committed to working with the entire healthcare community to ensure continued innovation and to facilitate patient access to needed medicines. We do this by:

- investing billions of dollars annually in R&D;
- developing more affordable therapeutic choices in the form of high-quality and reliably-supplied biosimilars;

- pricing our medicines to reflect the value they provide;
- partnering with payers to share risk and accountability for health outcomes;
- providing patient support and education programs and helping patients in financial need access our medicines; and
- working with policy makers, patients and other stakeholders to establish a sustainable healthcare system with access to affordable care and where patients and their healthcare professionals are the primary decision makers.

See Item 1A. Risk Factors—*Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability* and Item 1A. Risk Factors—*Guidelines and recommendations published by various organizations can reduce the use of our products.*

Manufacturing, Distribution and Raw Materials

Manufacturing

We believe we are a leader in the manufacturing of biologics and that our manufacturing capabilities represent a competitive advantage. The products we manufacture consist of both biologics and small-molecule drugs. The majority of our products are biologics that are produced in living cells and that are inherently complex due to naturally-occurring molecular variations. Highly specialized knowledge and extensive process and product characterization are required to transform laboratory-scale processes into reproducible commercial manufacturing processes. Further, our expertise in manufacturing of biologics positions us well for leadership in the global biosimilars market. For additional information regarding manufacturing facilities, see Item 2. Properties.

Our internal manufacturing network has the commercial production capabilities of bulk manufacturing, formulation, fill, finish and device assembly. These activities are performed within the United States and its territories in our Puerto Rico, Rhode Island and California facilities as well as internationally in our Ireland, Netherlands and Singapore facilities. In addition, we utilize third-party contract manufacturers to supplement the capacity or capability of our commercial manufacturing network.

To support our clinical trials, we manufacture product candidates primarily at our California and, to a lesser extent, our Rhode Island facilities. We also utilize third-party contract manufacturers for certain clinical products.

See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

Distribution

We operate distribution centers in Puerto Rico, Kentucky, California and the Netherlands for worldwide distribution of the majority of our commercial and clinical products. We also use third-party distributors to supplement distribution of our products worldwide.

Other

In addition to the manufacturing and distribution activities noted above, each of our manufacturing locations also includes key manufacturing support functions, including quality control, process development, procurement, production scheduling and warehousing. Certain of those manufacturing and distribution activities are highly regulated by the FDA as well as other international regulatory agencies. See Government Regulation—Regulation in the United States—Regulation of Manufacturing Standards.

Manufacturing Initiatives

We have multiple ongoing initiatives that are designed to extend our manufacturing advantage by optimizing our manufacturing network and/or mitigating risks while continuing to ensure adequate supply of our products.

In 2017, our next-generation biomanufacturing plant in Singapore was licensed by the FDA and the EMA for certain commercial-scale production. In 2018, we successfully completed additional bulk process qualification campaigns, which if approved, would permit the commercial production of an additional product at that site. A next-generation biomanufacturing plant incorporates multiple innovative technologies into a single facility and therefore can be built in half the construction time with approximately one-half of the operating cost of a traditional plant. Next-generation biomanufacturing plants require a smaller manufacturing footprint and offer greater environmental benefits, including reduced consumption of water and energy and lower levels of carbon emissions. Within the plant, the equipment is portable and smaller, and some components are disposable, which provides greater flexibility and speed when manufacturing different medicines simultaneously. This eliminates costly and complex retrofitting inherent in standard plants and allows Amgen to respond to changing demands for its medicines with increased agility, ultimately impacting the speed at which a medicine is available for patients. The Singapore site also has a plant with the capability to produce small-molecule drugs. When approved by relevant regulatory authorities this plant can be used for commercial manufacturing.

In July 2018, we announced the groundbreaking of our new next-generation biomanufacturing plant that will be constructed at our West Greenwich, Rhode Island, campus. The new plant is expected to be the first of its kind in the United States and will use our next-generation biomanufacturing capabilities. After construction has been completed

and upon approval by the FDA and other global regulatory authorities, this plant will expand our capacity to manufacture certain products for U.S. and global markets.

See Item 1A. Risk Factors—*Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

Raw Materials and Medical Devices

Certain raw materials, medical devices (including companion diagnostics) and components necessary for the commercial and/or clinical manufacturing of our products are provided by and are the proprietary products of unaffiliated third-party suppliers, certain of which may be our only sources for such materials. We currently attempt to manage the risk associated with such suppliers by inventory management, relationship management and evaluation of alternative sources when feasible. We also monitor the financial condition of certain suppliers and their ability to supply our needs. See Item 1A. Risk Factors—*We rely on third-party suppliers for certain of our raw materials, medical devices and components.*

We perform various procedures to help authenticate the source of raw materials, including intermediary materials used in the manufacture of our products, which include verification of the country of origin. The procedures are incorporated into the manufacturing processes we and our third-party contract manufacturers perform.

Government Regulation

Regulation by government authorities in the United States and other countries is a significant factor in the production and marketing of our products and our ongoing R&D activities. In order to clinically test, manufacture and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. Compliance with these standards is complex, and failure to comply with any of these standards can result in significant implications. See Item 1A. Risk Factors for a discussion of factors, including global regulatory implications, that can adversely impact our development and marketing of commercial products.

Regulation in the United States

In the United States, the Public Health Service Act, the Federal Food, Drug, and Cosmetic Act (FDCA) and the regulations promulgated thereunder, as well as other federal and state statutes and regulations govern, among other things, the production, research, development, testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising, promotion and distribution of our products, as well as the reporting of certain payments and other transfers of value to healthcare professionals and teaching hospitals.

Clinical Development and Product Approval. Drug development in our industry is complex, challenging and risky; and failure rates are high. Product development cycles are typically very long—approximately 10 to 15 years from discovery to market. A potential new medicine must undergo many years of preclinical and clinical testing to establish its safety and efficacy for use in humans at appropriate dosing levels and with an acceptable risk-benefit profile.

After laboratory analysis and preclinical testing in animals, we file an Investigational New Drug Application (IND) with the FDA to begin human testing. Typically, we undertake an FDA-designated three-phase human clinical testing program.

- In phase 1, we conduct small clinical trials to investigate the safety and proper dose ranges of our product candidates in a small number of human subjects.

- In phase 2, we conduct clinical trials to investigate side-effect profiles and the efficacy of our product candidates in a large number of patients who have the disease or condition under study.

- In phase 3, we conduct clinical trials to investigate the safety and efficacy of our product candidates in a large number of patients who have the disease or condition under study.

The FDA monitors the progress of each trial conducted under an IND and may, at its discretion, reevaluate, alter, suspend or terminate the testing based on the data accumulated to that point and the FDA's risk-benefit assessment with regard to the patients enrolled in the trial. The results of preclinical and clinical trials are submitted to the FDA in the form of either a BLA for biologic products or a New Drug Application for small-molecule products. We are not permitted to market or promote a new product until the FDA has approved our marketing application.

Approval of Biosimilars. The ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. The pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on the nonclinical and clinical trial data of an originator product to which the biosimilar has been demonstrated to be

“highly similar” and to have no clinically meaningful differences in terms of safety, purity and potency. The relevance of demonstrating “similarity” is that in many cases, biosimilars can be brought to market without conducting the full suite of clinical trials typically required of originators, as risk-benefit has previously been established. In order to preserve incentives for future innovation, the law establishes a period of exclusivity for originators’ products, which in general prohibits biosimilars from gaining FDA approval based in part on reliance on or reference to the originator’s data in their application to the FDA for 12 years after initial FDA approval of the originator product. The law does not change the duration of patents granted on biologic products. The FDA has released a number of guidance documents as part of the implementation of the abbreviated approval pathway for biosimilars, some of which remain in draft form.

As of the end of 2018, 16 biosimilar applications have been approved by the FDA, including our products AMJEVITA™, a biosimilar candidate to HUMIRA® (adalimumab), and MVASI™, a biosimilar candidate to Avastin® (bevacizumab), as well as competitors to our products ENBREL, Aranesp®, EPOGEN®, NEUPOGEN® and Neulasta®. A number of manufacturers have announced the filing of marketing applications to the FDA under the biosimilar pathway, some of which are for biosimilars of our products.

Regulation of Product Marketing and Promotion. The FDA regulates the marketing and promotion of drug products. Our product promotion for approved product indications must comply with the statutory standards of the FDCA and the FDA's implementing regulations and guidance. The FDA's review of marketing and promotional activities encompasses, but is not limited to, direct-to-consumer advertising, healthcare-provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA may also review industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. The FDA may take enforcement action against a company for promoting unapproved uses of a product or for other violations of its advertising and labeling laws and regulations. Enforcement action may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with the FDA's regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators. Additionally, as described below, such failure may lead to additional liability under U.S. health care fraud and abuse laws.

Regulation of Manufacturing Standards. The FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of products prior to providing approval to market products. If after receiving approval from the FDA we make a material change in manufacturing equipment, location or process, additional regulatory review may be required. We also must adhere to current Good Manufacturing Practice regulations and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA conducts regular, periodic visits to reinspect our equipment, facilities, laboratories and processes following an initial approval.

Regulation of Combination Products. Combination products are defined by the FDA to include products composed of two or more regulated components (e.g., a biologic and/or drug and a device). Biologics/drugs and devices each have their own regulatory requirements, and combination products may have additional requirements. A number of our marketed products meet this definition and are regulated under this framework, and we expect that a number of our pipeline product candidates will be evaluated for regulatory approval under this framework as well.

Regulation outside the United States

In the European Union (EU) countries as well as Switzerland, Canada, Australia and Japan, regulatory requirements and approval processes are similar in principle to those in the United States.

In the EU, there are currently two potential tracks for seeking marketing approval for a product not authorized in any EU member state: a decentralized procedure and a centralized procedure. In the *decentralized procedure*, identical applications for marketing authorization are submitted simultaneously to the national regulatory agencies. Regulatory review is led by one member state (the reference-member state), and its assessment—based on safety, quality and efficacy—is reviewed and approved (assuming there are no concerns that the product poses a serious risk to public health) by the other member states from which the applicant is seeking approval (the concerned-member states). The decentralized procedure leads to a series of single national approvals in all relevant countries. In the *centralized procedure*, which is required of all products derived from biotechnology, a company submits a single MAA to the EMA, which conducts an evaluation of the dossier, drawing upon its scientific resources across Europe. If the drug product is proven to fulfill the requirements for quality, safety and efficacy, the EMA's CHMP adopts a positive opinion, which is transmitted to the EC for final decision on grant of the marketing authorization. While the EC generally follows the CHMP's opinion, it is not bound to do so. Subsequent commercialization is enabled by country-by-country reimbursement approval.

In the EU, biosimilars are approved under a specialized pathway of the centralized procedure. As with the U.S. pathway, applicants seek and obtain regulatory approval for a biosimilar once the data exclusivity period for the original reference product has expired relying in part on the data submitted for the originator product together with data evidencing that the biosimilar is "highly similar" in terms of quality, safety and efficacy to the original reference product authorized in the European Economic Area.

As a result of the United Kingdom's vote to leave the EU in March 2019, the EMA announced that it will relocate its headquarters from London to Amsterdam by March 30, 2019. While negotiations continue regarding the terms of the United Kingdom's withdrawal from the EU, the specific impact to the supervision, regulation and supply of medicines in the United Kingdom and Europe remain unclear.

Other countries such as Russia, Turkey and those in Latin America and the Middle East have review processes and data requirements similar to those of the EU and in some cases can rely on prior marketing approval from U.S. or EU regulatory authorities. The regulatory process in these countries may include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements.

In Asia Pacific, a number of countries such as China, Japan, South Korea and Taiwan may require local clinical trial data for bridging purposes as part of the drug registration process in addition to global clinical trials, which can add to overall drug development and registration timelines. In most of the Asian markets, registration timelines depend on marketing approval in the United States or the EU. In some markets in Asia, such as China, Thailand and Indonesia, the regulatory timelines can be less predictable. The regulatory process may also include manufacturing/ testing facility inspections, testing of drug product upon importation and other domestic requirements. Countries such as Australia and Japan have more mature systems that would allow for submissions in more competitive time frames. Regarding biosimilars, several of these countries have pathways to register biosimilars (e.g., South Korea, India, Australia, Singapore and Taiwan), and biosimilar products are already present on the markets (e.g., Australia and South Korea).

In some countries, such as Japan and those in the EU, medical devices may be subject to regulatory regimes whereby the manufacturer must establish that its medical device conforms to essential requirements set out in the law for the particular device category. For example, in the EU, with limited exceptions, medical devices placed on the market must bear the Conformité Européenne marking to indicate their conformity with legal requirements.

Post-approval Phase

After approval, we continue to monitor adverse events and product complaints reported following the use of our products through routine post-marketing surveillance and studies when applicable. We report such events to the appropriate regulatory agencies as required per local regulations for individual cases and aggregate reports. We proactively monitor (according to good pharmacovigilance practices) and ensure implementation of signal detection, assessment and the communication of adverse events that may be associated with the use of our products. We also proactively monitor product complaints through our quality systems, which includes assessing our drug delivery devices for device complaints, adverse events and malfunctions. We may also be required by regulatory agencies to conduct further clinical trials on our marketed products as a condition of their approval or to provide additional information on safety and efficacy. Health authorities, including the FDA, have authority to mandate labeling changes to products at any point in a product's lifecycle based on new safety information or as part of an evolving label change to a particular class of products.

Health authorities, including the FDA, also have the authority, before or after approval, to require companies to implement a risk management program for a product to ensure that the benefits of the drug outweigh the risks. Each risk management program is unique and varies depending on the specific factors required. In the United States, a risk management program is known as a risk evaluation and mitigation strategy (REMS) and we currently have REMS for Prolia®, Nplate® and BLINCYTO®.

Other Regulation

We are also subject to various laws pertaining to healthcare fraud and abuse, including anti-kickback laws and false-claims laws. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for or to induce the referral of business, including the purchase or prescribing of a particular drug that is reimbursed by a state or federal program. False-claims laws prohibit knowingly and willingly presenting or causing to be presented for payment to third-party payers (including Medicare and Medicaid), any claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as by the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). Liability under the false-claims laws may also arise when a violation of certain laws or regulations related to the underlying products (e.g., violations regarding improper promotional activity or unlawful payments) contributes to the submission of a false claim.

In 2012, Amgen entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services, which was formally closed out in August 2018. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that in the future our practices might be further challenged under anti-kickback or similar laws.

Additionally, the U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA arguably includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

Our business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or regulations.

Research and Development and Selected Product Candidates

We focus our R&D on novel human therapeutics for the treatment of serious illness. We capitalize on our strength in human genetics, novel biology and protein engineering. We leverage our biologic expertise and take a modality-independent approach to R&D. We use cutting-edge science and technology to study subtle biological mechanisms in search of therapies that will improve the lives of those who suffer from diseases. Our discovery research programs may therefore yield targets that lead to the development of human therapeutics delivered as large molecules, small molecules, other combination modalities or new modalities. Leveraging two decades of research at deCODE, a global leader in analyzing the human genome, we are reshaping our portfolio and increasingly focusing efforts on validated targets. Human genetic validation is used whenever possible in order to enhance the likelihood of success. For the years ended December 31, 2018, 2017 and 2016, our R&D expenses were $3.7 billion, $3.6 billion and $3.8 billion, respectively.

We have major R&D centers in Thousand Oaks and San Francisco, California; Cambridge, Massachusetts; Iceland; and the United Kingdom, as well as smaller research centers and development facilities globally. See Item 2. Properties.

Our clinical trial activities are conducted by both our internal staff and third-party contract clinical trial service providers. To increase the number of patients available for enrollment in our clinical trials, we have opened clinical sites and will continue opening clinical sites and enrolling patients in a number of geographic locations. See Government Regulation—Regulation in the United States—Clinical Development and Product Approval for a discussion of government regulation over clinical development. Also see Item 1A. Risk Factors—*We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.*

Some of our competitors are actively engaged in R&D in areas in which we have products or in which we are developing product candidates or new indications for existing products. For example, we compete with other clinical trials for eligible patients, which may limit the number of available patients who meet the criteria for certain clinical trials. The competitive marketplace for our product candidates is greatly dependent on the timing of entry into the market. Early entry may have important advantages in gaining product acceptance, thereby contributing to a product's eventual success and profitability. Accordingly, we expect that in some cases, the relative speed with which we can develop products, complete clinical testing, receive regulatory approval and supply commercial quantities of a product to the market will be important to our competitive position.

In addition to product candidates and marketed products generated from our internal R&D efforts, we acquire companies, acquire and license certain product and R&D technology rights and establish R&D arrangements with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. In pursuing these R&D arrangements and licensing or acquisition activities, we face competition from other pharmaceutical and biotechnology companies that also seek to license or acquire technologies, product candidates or marketed products from those entities performing the R&D.

The following table shows a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 12, 2019, unless otherwise indicated. Additional product candidate information can be found on our website at www.amgen.com. (The website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.) The information in this section does not include other, nonregistrational clinical trials that we may conduct for purposes other than for submission to regulatory agencies for their approval of a new product indication.

We may conduct nonregistrational clinical trials for various reasons, including to evaluate real-world outcomes or to collect additional safety information with regard to the use of our products. In addition, the table does not include biosimilar products we are developing, which are discussed later in this section.

Molecule	Disease/condition
Phase 3 Programs	
ENBREL	Rheumatoid arthritis remission
EVENITY™	Postmenopausal osteoporosis; Male osteoporosis
IMLYGIC®	Metastatic melanoma
KYPROLIS®	Multiple myeloma
Omecamtiv mecarbil	Chronic heart failure
Tezepelumab	Severe asthma
AMG 520 / CNP520	Alzheimer's disease
Phase 2 Programs	
BLINCYTO®	Diffuse large B-cell lymphoma
Tezepelumab	Atopic dermatitis
AMG 714 / PRV-015	Celiac disease
Phase 1 Programs	
IMLYGIC®	Various cancer types
AMG 119	Small-cell lung cancer
AMG 160	Prostate cancer
AMG 176	Hematologic malignancies
AMG 212	Prostate cancer
AMG 330	Acute myeloid leukemia
AMG 397	Hematologic malignancies
AMG 420	Multiple myeloma
AMG 424	Multiple myeloma
AMG 427	Acute myeloid leukemia
AMG 510	Solid tumors
AMG 562	Non-Hodgkin's lymphoma
AMG 570	Systemic lupus erythematosus
AMG 592	Inflammatory diseases
AMG 596	Glioblastoma
AMG 598	Obesity
AMG 673	Acute myeloid leukemia
AMG 701	Multiple myeloma
AMG 757	Small-cell lung cancer
AMG 890	Cardiovascular disease
AMG 966	Inflammatory bowel diseases (Crohn's and ulcerative colitis)
AMG 986	Heart failure

Phase 3 Clinical trials investigate the safety and efficacy of product candidates in a large number of patients who have the disease or condition under study; typically performed with registrational intent.

Phase 2 Clinical trials investigate side effect profiles and efficacy of product candidates in a large number of patients who have the disease or condition under study.

Phase 1 Clinical trials investigate the safety and proper dose ranges of product candidates in a small number of human subjects.

Phase 3 Product Candidate Program Changes

As of February 12, 2018, we had 13 phase 3 programs. As of February 12, 2019, we had eight phase 3 programs, as regulatory approvals were received for three programs, and two programs concluded. These changes are set forth in the following table.

Molecule	Disease/condition	Program change
Aimovig®	Migraine prevention	BLA approved by FDA
Aranesp®	Myelodysplastic syndromes	Concluded; no longer pursuing our marketing application with the EC
BLINCYTO®	ALL	sBLA approved by FDA
ENBREL	Psoriatic arthritis	Concluded; study achieved its primary endpoint
Prolia®	Glucocorticoid-induced osteoporosis	sBLA approved by FDA and EC

Phase 3 Product Candidate Patent Information

The following table describes our outstanding composition of matter patents that have been issued thus far for our product candidates in phase 3 development that have yet to be approved for any indication in the United States or the EU. Patents for products already approved for one or more indications in the United States or the EU but that are currently undergoing phase 3 clinical trials for additional indications are previously described. See Marketing, Distribution and Selected Marketed Products—Patents.

Molecule	Territory	General subject matter	Estimated expiration*
EVENITY™	U.S.	Polypeptides	2026
	Europe	Polypeptides	2026
Omecamtiv mecarbil	U.S.	Compound	2027
	Europe	Compound	2025
Tezepelumab	U.S.	Polypeptides	2029
	Europe	Polypeptides	2028
AMG 520 / CNP520	U.S.	Compound	2032
	Europe	Compound	2032

* Patent expiration estimates are based on issued patents, which may be challenged, invalidated or circumvented by competitors. The patent expiration estimates do not include any term adjustments, extensions or supplemental protection certificates that may be obtained in the future and extend these dates. Corresponding patent applications are pending in other jurisdictions. Additional patents may be filed or issued and may provide additional exclusivity for the product candidate or its use.

Phase 3 and 2 Program Descriptions

The following provides additional information about selected product candidates that have advanced into human clinical trials.

BLINCYTO®

BLINCYTO® is an anti-CD19 x anti-CD3 (BiTE®) bispecific antibody construct.

A phase 2/3 study in patients with relapsed or refractory diffuse large B-cell lymphoma is ongoing.

ENBREL

ENBREL is a fusion protein that inhibits tumor necrosis factor.

A phase 3 study to evaluate ENBREL as a monotherapy in maintaining remission in rheumatoid arthritis is ongoing.

EVENITY™

EVENITY™ is a humanized monoclonal antibody that inhibits the action of sclerostin. It is being evaluated as a treatment for osteoporosis. EVENITY™ is being developed in collaboration with UCB.

In January 2019, we and UCB announced support from the FDA BRUDAC for the approval of EVENITY™ for the treatment of postmenopausal women with osteoporosis at high risk for fracture. Also in January 2019, the Japanese Ministry of Health, Labor and Welfare granted a marketing authorization for EVENITY™ for the treatment of osteoporosis in men and postmenopausal women at high risk of fracture.

IMLYGIC®

IMLYGIC® is an oncolytic immunotherapy derived from herpes simplex virus type 1.

A phase 1b/3 study to evaluate IMLYGIC® in combination with Merck & Company, Inc.'s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with mid- to late-stage metastatic melanoma is ongoing.

KYPROLIS®

KYPROLIS® is a proteasome inhibitor.

In April 2018, we announced that the CHMP of the EMA adopted a positive opinion recommending a label variation for KYPROLIS® to include the final overall survival data from the phase 3 ASPIRE study.

In June 2018, we announced that the FDA approved the sNDA to add the positive overall survival data from the phase 3 ASPIRE study to the U.S. Prescribing Information for KYPROLIS® in patients with relapsed or refractory multiple myeloma.

In October 2018, we announced that the FDA approved the sNDA to expand the Prescribing Information for KYPROLIS® to include a once-weekly dosing option in combination with dexamethasone for patients with relapsed or refractory multiple myeloma.

A phase 3 study comparing carfilzomib, dexamethasone, and daratumumab to carfilzomib and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma is ongoing.

Omecamtiv mecarbil

Omecamtiv mecarbil is a small-molecule activator of cardiac myosin. It is being evaluated for the treatment of chronic heart failure. Omecamtiv mecarbil is being developed by Amgen in collaboration with Cytokinetics, Inc., and in collaboration with Servier for certain territories.

A phase 3 cardiovascular outcomes study for the treatment of chronic heart failure is ongoing.

Tezepelumab

Tezepelumab is a human monoclonal antibody that inhibits the action of thymic stromal lymphopoietin. It is being evaluated as a treatment for severe asthma in an ongoing phase 3 study, as well as atopic dermatitis. Tezepelumab is being developed jointly in collaboration with AstraZeneca.

AMG 520 / CNP520

AMG 520 / CNP520 is a small-molecule inhibitor of beta-site amyloid precursor protein-cleaving enzyme-1 (BACE). It is being evaluated for the prevention of Alzheimer's disease, with phase 3 studies ongoing. AMG 520 / CNP520 is being developed jointly in collaboration with Novartis.

AMG 714 / PRV-015

AMG 714 / PRV-015 is a human monoclonal antibody that binds to Interleukin-15. It is being investigated for the treatment of celiac disease. In November 2017, Amgen reacquired the AMG 714 program from Celimmune LLC. AMG 714 / PRV-015 is being developed jointly in collaboration with Provention Bio.

Amgen Development of Biosimilars

We also develop and commercialize biosimilar medicines. Our biosimilar product candidates in late-stage clinical development are described in the following table:

Program	Reference product	Status
ABP 710	Infliximab (REMICADE®)	Filed BLA with the FDA and MAA with the EMA
ABP 798	Rituximab (Rituxan® / Mabthera®)	Phase 3 rheumatoid arthritis study completed Phase 3 non-Hodgkin's lymphoma study ongoing
ABP 959	Eculizumab (Soliris®)	Phase 3 initiated

In addition to the above programs, AMJEVITA™ / AMGEVITA™ and MVASI™ have been approved by the FDA and the EC. KANJINTI™ has been approved by the EC and we have refiled our BLA with the FDA. We are also pursuing other biosimilar product candidates in earlier-stage development.

Business Relationships

From time to time, we enter into business relationships, including joint ventures and collaborative arrangements, for the R&D, manufacture and/or commercialization of products and/or product candidates. In addition, we acquire product and R&D technology rights and establish R&D collaborations with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. These arrangements generally provide for nonrefundable, upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. The activities under these collaboration agreements are performed with no guarantee of either technological or commercial success, and each is unique in nature.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require counterparties to execute confidentiality agreements upon commencement of a business relationship with us. However, others could either develop independently the same or similar information or unlawfully obtain access to our information.

Kirin-Amgen, Inc.

During the first quarter of 2018, we acquired the remaining 50% ownership interest of Kirin-Amgen, Inc. (K-A), from Kirin Holdings Company, Limited (Kirin), making K-A a wholly owned subsidiary of Amgen. Prior to the closing of the share acquisition, K-A was a 50-50 joint venture with Kirin. K-A develops and then licenses all product rights that have been transferred from Amgen and Kirin. See Part IV—Note 3, Business combinations and Note 10, Related party transactions, to the Consolidated Financial Statements.

Prior to the closing of the share acquisition, K-A had given us exclusive licenses to manufacture and market (i) filgrastim and pegfilgrastim in the United States; Europe; Canada; Australia; New Zealand; all Central American, South American, Middle Eastern and African countries; and certain countries in Asia; (ii) darbepoetin alfa and romiplostim in the United States; Europe; Canada; Australia; New Zealand; Mexico; all Central and South American countries and certain countries in Central Asia, Africa and the Middle East; and (iii) recombinant human erythropoietin in the United States. We currently market pegfilgrastim, filgrastim, darbepoetin alfa, recombinant human erythropoietin and romiplostim under the brand names Neulasta®, NEUPOGEN®/GRANULOKINE®, Aranesp®, EPOGEN® and Nplate®, respectively. Under these agreements, Amgen paid K-A royalties based on product sales. In addition, Amgen received payments from K-A for milestones earned and for conducting certain R&D activities on K-A's behalf.

K-A has also given and continues to grant Kirin exclusive licenses to manufacture and market (i) filgrastim and pegfilgrastim in Japan, Taiwan and South Korea; (ii) darbepoetin alfa, romiplostim and brodalumab in Japan, China, Taiwan, South Korea and certain other countries and/or regions in Asia; and (iii) recombinant human erythropoietin in Japan. K-A also gave Kirin and Amgen co-exclusive licenses to manufacture and market filgrastim, pegfilgrastim and recombinant human erythropoietin in China, which Amgen subsequently assigned to Kirin, and as a result, Kirin now manufactures and markets filgrastim and recombinant human erythropoietin exclusively in China. Kirin markets filgrastim, pegfilgrastim, darbepoetin alfa, romiplostim, recombinant human erythropoietin and brodalumab under the brand names GRAN®/Grasin®, Peglasta®/Neulasta®/G-Lasta®, NESP®/Aranesp®, ROMIPLATE®, ESPO® and LUMICEF®, respectively. Under these agreements, Kirin pays K-A royalties based on product sales. In addition, Kirin receives payments from K-A for conducting certain R&D activities on K-A's behalf.

Novartis

In April 2017, we expanded our existing migraine collaboration with Novartis. In the United States, Amgen and Novartis jointly develop and collaborate on the commercialization of Aimovig®. Amgen, as the principal, recognizes product sales of Aimovig® in the United States, shares U.S. commercialization costs with Novartis and pays Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig® and other specified migraine programs. Novartis pays Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories and funds a portion of global R&D expenses. In addition, Novartis will make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds are achieved with respect to Aimovig® in the United States. Amgen manufactures and supplies Aimovig® worldwide.

UCB

We are in a collaboration with UCB for the development and commercialization of EVENITY™. Under our collaboration, UCB has the rights to lead commercialization for EVENITY™ for all indications in Europe, China (excluding Hong Kong) and Brazil. All other territories have been allocated to Amgen. Generally, development costs and future worldwide commercialization profits and losses related to the collaboration after accounting for expenses are shared equally.

Bayer HealthCare Pharmaceuticals Inc.

We are in a collaboration with Bayer HealthCare Pharmaceuticals Inc. (Bayer) to jointly develop and commercialize Nexavar® (sorafenib). In 2015, we amended the terms of our collaboration agreement with Bayer, which terminated the co-promotion agreement in the United States and transferred all U.S. operational responsibilities to Bayer, including commercial and medical affairs activities. Prior to the termination of the co-promotion agreement, we co-promoted Nexavar® with Bayer and shared equally in the profits in the United States. In lieu of this profit share, Bayer now pays us a royalty on U.S. sales of Nexavar® at a percentage rate in the high 30s. Outside the United States and Japan, Bayer manages all commercialization activities and incurs all sales and marketing expenditures and mutually agreed R&D expenses, and we reimburse Bayer for half of those expenditures. In all countries outside the United States and Japan, we receive 50% of net profits on sales of Nexavar® after deducting certain Bayer-related costs. The rights to develop and market Nexavar® in Japan are reserved to Bayer.

DaVita Inc.

In January 2017, we entered into a six-year supply agreement with DaVita Inc. (DaVita), which superseded the previously existing seven-year supply agreement that commenced in 2012. Pursuant to the 2017 agreement, we supply EPOGEN® and Aranesp® in amounts necessary to meet specified annual percentages of DaVita's and its affiliates' requirements for erythropoiesis-stimulating agents (ESAs) used in providing dialysis services in the United States and Puerto Rico. Such percentage varies during the term of the agreement, but in each year is at least 90%. The agreement expires in 2022. The agreement may be terminated by either party before expiration of its term in the event of certain breaches of the agreement by the other party.

Human Resources

As of December 31, 2018, Amgen had approximately 21,500 staff members. We consider our staff relations to be good.

Executive Officers of the Registrant

Mr. Robert A. Bradway, age 56, has served as a director of the Company since 2011 and Chairman of the Board of Directors since 2013. Mr. Bradway has been the Company's President since 2010 and Chief Executive Officer since 2012. From 2010 to 2012, Mr. Bradway served as the Company's President and Chief Operating Officer. Mr. Bradway joined the Company in 2006 as Vice President, Operations Strategy, and served as Executive Vice President and Chief Financial Officer from 2007 to 2010. Prior to joining the Company, he was a Managing Director at Morgan Stanley in London, where, beginning in 2001, he had responsibility for the firm's banking department and corporate finance activities in Europe. Mr. Bradway has been a director of The Boeing Company, an aerospace company and manufacturer of commercial airplanes, defense, space and securities systems, since 2016. He has served on the board of trustees of the University of Southern California since 2014 and on the advisory board of the Leonard D. Schaeffer Center for Health Policy and Economics at that university since 2012. From 2011 to 2017, Mr. Bradway was a director of Norfolk Southern Corporation, a transportation company.

Mr. Murdo Gordon, age 52, became Executive Vice President, Global Commercial Operations in 2018. Prior to joining the Company, Mr. Gordon was the Chief Commercial Officer at Bristol-Myers Squibb Company (BMS) from 2016 to July 2018. Mr. Gordon served as Head of Worldwide Markets at BMS from 2015 to 2016. Prior to this, Mr. Gordon served in a variety of leadership roles at BMS for over 25 years.

Mr. Jonathan P. Graham, age 58, became Senior Vice President, General Counsel and Secretary in 2015. From 2006 to 2015, Mr. Graham was Senior Vice President and General Counsel at Danaher Corporation. From 2004 to 2006, Mr. Graham was Vice President, Litigation and Legal Policy, at General Electric Company (GE). Prior to GE, Mr. Graham was a partner at Williams & Connolly LLP.

Ms. Lori A. Johnston, age 54, became Senior Vice President, Human Resources in 2016. From 2012 to 2016, Ms. Johnston was Executive Vice President and Chief Administrative Officer of Celanese Corporation. From 2006 to 2012, Ms. Johnston served in a series of progressive leadership roles at the Company, with her last position being Vice President, Human Resources. Prior to joining the Company, Ms. Johnston held human resources and other positions at Dell Inc.

Mr. David W. Meline, age 61, became Executive Vice President and Chief Financial Officer in 2014. From 2011 to 2014, Mr. Meline served as Senior Vice President and Chief Financial Officer at 3M Company (3M). From 2008 to 2011, Mr. Meline served as Vice President, Corporate Controller and Chief Accounting Officer of 3M. Prior to 2008, Mr. Meline served in a variety of senior leadership roles at General Motors Company for over 20 years, with his last position being Vice President and Chief Financial Officer, North America. Mr. Meline has been a director of ABB Ltd., a global industrial technology company based in Switzerland, since 2016, currently serving as the chairman of the Finance, Audit and Compliance Committee. Mr. Meline was a director of TRW Automotive Holdings, Corp., a supplier of automotive systems, modules and components, from 2014 until its acquisition by ZF Friedrichshafen AG in 2015.

Ms. Cynthia M. Patton, age 57, became Senior Vice President and Chief Compliance Officer in 2012. Ms. Patton joined the Company in 2005. From 2005 to 2010, Ms. Patton was Associate General Counsel. From 2010 to 2012, Ms. Patton was Vice President, Law. Previously, Ms. Patton served as Senior Vice President, General Counsel and Secretary of SCAN Health Plan from 1999 to 2005.

Mr. David A. Piacquad, age 62, became Senior Vice President, Business Development, in 2014. Mr. Piacquad joined the Company in 2010 and served as Vice President, Strategy and Corporate Development, until 2014. Mr. Piacquad served as Vice President, Business Development in 2014. Prior to joining the Company, from 2009 to 2010 Mr. Piacquad was Principal of David A. Piacquad Consulting LLC. From 2006 to 2009, Mr. Piacquad served as Senior Vice President, Business Development and Licensing at Schering-Plough Corporation (Schering-Plough). Prior to Schering-Plough, Mr. Piacquad served in a series of leadership roles in finance and business development at J&J, with his last position being Vice President, Ventures and Business Development.

Dr. David M. Reese, age 56, became Executive Vice President, Research and Development in 2018. Dr. Reese joined the Company in 2005 and has held leadership roles in development, medical sciences and discovery research. Dr. Reese was Senior Vice President, Translational Sciences and Oncology, from 2017 to 2018 and Senior Vice President, Translational Sciences, from 2015 to 2017. Prior to joining Amgen, Dr. Reese was director of Clinical Research for the Breast Cancer International Research Group from 2001 to 2003 and a co-founder, president and chief medical officer of Translational Oncology Research International, a not-for-profit academic clinical research organization from 2003 to 2005. Dr. Reese previously served on the faculty at University of California, Los Angeles and the University of California, San Francisco.

Mr. Esteban Santos, age 51, became Executive Vice President, Operations, in 2016. Mr. Santos joined the Company in 2007 as Executive Director, Manufacturing Technologies. From 2008 to 2013, Mr. Santos held a number of Vice President roles at the Company in engineering, manufacturing, site operations and drug product. From 2013 to 2016, Mr. Santos was Senior Vice President, Manufacturing. Prior to joining the Company, Mr. Santos served as Site General Manager of J&J's Cordis operation in Puerto Rico. Prior to J&J, Mr. Santos held several management positions in GE's industrial and transportation businesses.

Geographic Area Financial Information

For financial information concerning the geographic areas in which we operate, see Part IV—Note 4, Revenues and Note 13, Property, plant and equipment, to the Consolidated Financial Statements.

Investor Information

Financial and other information about us is available on our website at www.amgen.com. We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission (SEC). In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected, without charge, at the SEC's website at www.sec.gov. (These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.)

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability.

Sales of our products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers continue to pursue initiatives to contain costs and manage drug utilization. These payers are increasingly focused on the effectiveness, benefits and costs of similar treatments, which could result for our products in lower reimbursement rates or narrower populations for whom payers will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payer dynamics, may limit our ability to set or adjust the price of our products based on their value, which could have a material adverse effect on our business. In the United States, the public discussions of drug pricing issues are likely to continue.

—Changing federal coverage and reimbursement policies and practices have impacted and may continue to impact access to and sales of our products

A substantial portion of our U.S. business relies on reimbursement from U.S. federal government healthcare programs and commercial insurance plans regulated by the U.S. federal and state governments. See Item 1. Business —Reimbursement. Our business has and will continue to be impacted by legislative actions changing U.S. federal reimbursement policy. For example, in February 2018, the U.S. Congress passed legislation requiring biopharmaceutical manufacturers to provide greater discounts beginning in 2019 on products dispensed to patients in the coverage gap between the initial coverage limit of Medicare Part D and the program's catastrophic-coverage threshold, which will reduce our net product sales relating to such patients. Additional legislative proposals have been introduced by members of Congress to overhaul provisions of the Patient Protection and ACA, to allow commercial-level re-importation of prescription medications from Canada or other countries and to enable Medicare to negotiate drug prices with biopharmaceutical manufacturers. Congressional focus on drug pricing has increased since the Democrats took control of the U.S. House of Representatives in November 2018. For example, in January 2019, the chair of the House Oversight and Reform Committee sent letters to twelve different biopharmaceutical manufacturers, including Amgen, seeking documents and detailed information about such companies' drug pricing. Both that committee and the Senate Finance Committee held committee hearings in January 2019 on the topic of drug pricing and have indicated that further committee hearings on the topic are likely.

Also our business has been and is expected to continue to be impacted by changes in U.S. federal reimbursement policy resulting from executive actions, federal regulations, or federal demonstration projects. For example, in May 2018, the U.S. presidential administration released a drug pricing "blueprint" and requested public comment on an array of policy ideas intended to increase competition, improve the negotiating power of the federal government, reduce drug prices and lower patient out-of-pocket costs. This blueprint includes a number of policy ideas with the potential to significantly impact, whether individually or collectively, our industry. Such proposals include moving coverage and reimbursement for Medicare Part B drugs into Medicare

Part D, instituting a competitive acquisition program for Part B drugs in which competing third-party vendors take on the financial risk of acquiring drugs and billing Medicare, removing the safe harbor protection under the federal anti-kickback statute for drug rebates paid to payers, and requiring the inclusion of drug price information in direct-to-consumer drug advertising.

Since that time, the president and/or federal agencies, such as CMS, have announced a number of demonstration projects, recommendations and proposals to implement various elements described in the drug pricing blueprint. CMS, the federal agency responsible for administering Medicare and overseeing state Medicaid programs and Health Insurance Marketplaces, has substantial power to implement policy changes or demonstration projects that can quickly and significantly affect how drugs, including our products, are covered and reimbursed. For example, in October 2018, President Trump announced that CMS was evaluating a pilot program proposed to initially cover fifty percent of spending on Part B single-source drugs referred to as the "International Price Index" that would, among other things, set the Medicare payment amount for such single-source drugs to more closely align with international drug prices. CMS has taken additional actions to implement other elements described in the administration's drug-pricing blueprint, including issuing guidance to allow certain Medicare plans offered by private insurance companies to require that patients receiving Medicare Part B drugs first try a drug preferred by the plan before such plan will cover another therapy and proposing lower reimbursement rates for new Part B drugs. And on January 31, 2019, the U.S. Department of Health and Human Services released a proposal to revise the federal anti-kickback statute safe harbor regulations to exclude from safe harbor protection certain rebates and other forms of remuneration paid by a manufacturer of prescription drugs to Medicaid managed care organizations or plan sponsors under Medicare Part D, either directly or through PBMs.

Further, CMS has undertaken demonstration projects to test care models, such as the CMS Oncology Care Model, which provides participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare costs without negatively impacting the efficacy of care. We believe the Oncology Care Model has reduced utilization of certain of our oncology products by participating physician practices and may continue to do so in the future. In addition, CMS has solicited suggestions regarding other potential care models.

In this dynamic environment, we are unable to predict which or how many of these various federal policy, legislative or regulatory changes may ultimately be enacted, to the extent that these or other federal government initiatives decrease or modify the coverage or reimbursement available for our products, limit our ability to offer co-pay payment assistance to commercial patients, require that we pay increased rebates or shift other costs to us, limit or impact our decisions regarding the pricing of biopharmaceutical products or otherwise reduce the use of our U.S. products, such actions could have a material adverse effect on our business and results of operations.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products. Government price reporting regulations are complex and may require a manufacturer to update certain previously submitted data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data, we also may be required to pay additional rebates and provide additional discounts.

—Changing state reimbursement and pricing actions may impact access to and have impacted and may continue to impact sales of our products

At the state level, government actions or ballot initiatives can also affect how our products are covered and reimbursed and/or create additional pressure on our pricing decisions. A number of states have adopted, and many other states have discussed and debated and are considering, new pricing actions, including proposals designed to require biopharmaceutical manufacturers to publicly report proprietary pricing information, limit price increases or to place a maximum price ceiling or cap on biopharmaceutical products. Existing and proposed state pricing laws have added complexity to the pricing of drugs and may already be impacting industry pricing decisions. For example, in October 2017, California enacted a drug-pricing transparency bill that requires biopharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. Other states are seeking to change the way their states pay for drugs for patients covered by state programs. For example, in August 2018 the Ohio Department of Medicaid ordered that all the state's Medicaid managed care plans terminate and renegotiate contracts with PBMs to eliminate the drug purchasing model in which PBMs bill the state more than they reimburse pharmacists for filling Medicaid patient prescriptions. In January 2019, California's governor issued an executive order expanding state Medicaid coverage and directing state agencies and programs to consolidate drug purchases and to negotiate drug prices with manufacturers. Other states could adopt similar approaches or could pursue different policy changes in a continuing effort to reduce their costs.

Ultimately, as with U.S. federal government actions, existing or future state government actions or ballot initiatives may also have a material adverse effect on our product sales, business and results of operations.

—U.S. commercial payer actions have impacted and may continue to impact access to and sales of our products

Payers, including healthcare insurers, PBMs and group purchasing organizations, increasingly seek ways to reduce their and their respective members' costs. With increasing frequency, payers are adopting benefit plan changes that shift a greater portion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient co-pay or coinsurance obligations and limitations on patients' use of manufacturer commercial co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs). Payers have sought and will likely continue to seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage, particularly in treatment areas where the payer has taken the position that multiple branded products are therapeutically comparable. Payers also control costs by imposing restrictions on access to or usage of our products, such as requiring that patients first try a drug preferred by the payer or receive the payer's prior authorization before covering the product, or that patients use a mail-order pharmacy or mail-order pharmacy or a limited network of fully-owned specialty pharmacies; payers may also choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. For example, the burdensome administrative processes required for physicians to demonstrate or document that the patients for whom Repatha® has been prescribed meet payer utilization management criteria has limited and may continue to limit patient access to Repatha® treatment. In an effort to reduce barriers to access, we reduced the net price of Repatha® by providing greater discounts and rebates to payers, including PBMs that administer Medicare Part D prescription drug plans. However, affordability of patient out-of-pocket co-pay cost has and may continue to limit patient use. For example, a very high percentage of Medicare patients have abandoned their Repatha® prescriptions rather than pay their co-pay payment. In late 2018 and early 2019, we introduced a set of new NDCs to make Repatha® available at a lower list price to attempt to address affordability for patients, particularly those on Medicare. Despite the recent net and list price reductions, payers may continue to restrict patient access, change formulary coverage for Repatha®, seek further discounts or rebates or take other actions that could reduce our sales of Repatha®. Further, our introduction of the new NDCs may not be rapidly adopted by payers, which could continue to limit patient use and could also reduce our sales of Repatha®.

Significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. For example, in the United States, the top three PBMs now oversee greater than two-thirds of prescription claims as well as government and commercial covered lives. The consolidation among insurers, PBMs and other payers, including through integrated delivery systems and/or with specialty or mail-order pharmacies and pharmacy retailers, has increased the negotiating leverage such entities have over us and other drug manufacturers and has resulted in greater price discounts, rebates and fees for other services being realized by those payers. For example, during the fourth quarter of 2018, two of the nation's largest PBMs, Express Scripts and CVS Health, completed their combinations with major insurance companies Cigna and Aetna, respectively. Additional consolidation would further increase the leverage of such entities. Ultimately, additional discounts, rebates, coverage or plan changes, restrictions or exclusions imposed by these commercial payers could have a material adverse effect on our product sales, business and results of operations.

—Government and commercial payer actions outside the United States have impacted and will continue to impact access to and sales of our products

Outside the United States, we expect countries will continue to take actions to reduce their drug expenditures. See Item 1. Business—Reimbursement. International reference pricing (IRP) has been widely used by many countries outside the United States to control costs based on an external benchmark of a product's price in other countries. IRP policies can quickly and frequently change and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. In addition, countries may refuse to reimburse or may restrict the reimbursed population for a product when their national health technology assessments do not consider a medicine to demonstrate sufficient clinical benefit beyond existing therapies or that it does not meet certain cost effectiveness thresholds. For example, despite the EMA's May 2018 approval of Repatha® for the treatment of patients with established atherosclerotic disease, reimbursement for Repatha® in France and Germany has remained limited to narrower patient populations (such as those with homozygous familial hypercholesterolemia) following national health technology assessments in mid-2018. While the pricing and reimbursement process in those countries remains ongoing, these assessments currently limit our efforts in France and Germany to expand Repatha® access to the broader patient population covered by the approved label. Failure to obtain coverage and reimbursement for our products, a deterioration in their existing coverage and reimbursement, or a decline in the timeliness or certainty of payment by payers to physicians and other providers could negatively impact the ability or willingness of healthcare providers to prescribe our products for their patients or could

otherwise negatively affect the use of our products or the prices we receive for them. Such changes could have a material adverse effect on our product sales, business and results of operations.

We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future.

We currently face competition from biosimilars in both Europe and the United States, and we expect to face increasing biosimilar and/or generics competition this year and beyond. Expiration or successful challenge of applicable patent rights or

expiration of an applicable exclusivity period would accelerate such competition, and we expect to face more litigation regarding the validity and/or scope of our patents. Our products may also experience greater competition from lower-cost biosimilars or generics that come to market when branded products that compete with our products lose their own patent protection. To the extent that governments adopt more permissive approval frameworks and competitors are able to obtain broader or expedited marketing approval for biosimilars and generics, the rate of increased competition for our products could accelerate.

In the EU, biosimilars are evaluated for marketing authorization pursuant to a set of general and product class-specific guidelines. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU countries have adopted and others are attempting to adopt biosimilar uptake measures such as requiring physician prescribing quotas or promoting switching or pharmacy substitution of biosimilars for the corresponding reference products, and other countries may adopt similar measures. Some EU countries impose automatic price reductions upon market entry of one or more biosimilar competitors. While the degree of competitive impact of biosimilar competition differs between EU countries and between products, in the EU the overall use of biosimilars and the rate at which product sales of innovative products are being impacted by biosimilar competition is increasing.

In the United States, the ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. See Item 1. Business—Government Regulation—Regulation in the United States—Approval of Biosimilars. The first biosimilar entrant into the U.S. market, Sandoz's Zarxio®, is a biosimilar version of NEUPOGEN® and was launched in the United States in 2015. Since then, the FDA has approved additional biosimilars, including biosimilar versions of ENBREL, Neulasta® and EPOGEN®, and a growing number of companies have announced that they are also developing biosimilar versions of our products. Two biosimilar versions of Neulasta® are now marketed in the United States and others may receive approval in 2019. Impact to our Neulasta® sales could accelerate as additional competitors are launched. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. The approved biosimilar version of EPOGEN® has also launched in the United States, and we are currently involved in patent litigation with the manufacturer of the approved version of ENBREL. Manufacturers of biosimilars may attempt to compete with our products by offering lower list prices, greater discounts or rebates, or contracts that offer longer-term pricing or a broader portfolio of other products. Companies pursuing development of biosimilar versions of our products have challenged and may continue to challenge our patents well in advance of the expiration of our material patents. For information related to our biosimilars and generics patent litigation, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements. See *Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in present and future intellectual property litigation.* The U.S. pathway includes the option for biosimilar products that meet certain criteria to be approved as interchangeable with their reference products. Some companies currently developing or already marketing biosimilars may seek to register their products as interchangeable biosimilars, which could make it easier for pharmacists to substitute those biosimilars for our reference products or could encourage prescribers or payers who are inclined to select the interchangeable biosimilar over our innovative products or our biosimilars. In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law's provisions regarding which new products receive data exclusivity. For example, the FDA is considering whether subsequent changes to a licensed biologic would be protected by the remainder of the reference product's original 12-year exclusivity period (a concept known in the generic drug context as "umbrella exclusivity"). If the FDA were to decide that umbrella exclusivity does not apply to biological reference products or were to make other changes to the exclusivity period, this could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, public, legislative, and FDA efforts to promote price competition through policies enabling easier generic and biosimilar entry, including efforts to lower standards for demonstrating biosimilarity or interchangeability and provide greater clarity for how to do so, and through changes to the reimbursement policies for biologics.

Upon the expiration or loss of patent protection for one of our small-molecule products, we can lose the majority of revenues for that product in a very short period of time. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. Our U.S. composition of matter patent for Sensipar®, a small-molecule product, expired in March 2018. We are engaged in litigation with a number of companies seeking to market generic versions of Sensipar® surrounding our U.S. formulation patent that expires in September 2026. Several of these generic versions of Sensipar® have been approved by the FDA, and the manufacturer of one of the approved generic versions began selling its product in late 2018 before reaching a settlement agreement with us in early January 2019. We were subsequently sued by a manufacturer of another approved generic version of Sensipar® who is contending that provisions of its own settlement agreement with Amgen have been triggered by the first manufacturer's at-risk launch, giving this second manufacturer a right to market its own generic version under its settlement agreement. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial

Statements. While no generic versions of Sensipar® are currently available for sale, one or more other companies may elect to launch their approved generic versions at-risk prior to the conclusion of our ongoing litigation, or may seek and obtain a judicial declaration that they are permitted to launch their generic versions. If this happens, our product sales for Sensipar® could be materially and adversely affected.

While we are unable to predict the precise impact of biosimilars and generics on our products, we are currently facing and expect to face greater competition in the United States, Europe and elsewhere this year and beyond as a result of biosimilar and

generic competition and downward pressure on our product prices and sales. This competition has had and could increasingly have a material adverse effect on our product sales, business and results of operations.

Our products face substantial competition.

We operate in a highly competitive environment. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We expect that our products will compete with new drugs currently in development, drugs currently approved for other indications that may later be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. Large pharmaceutical companies and generics manufacturers of pharmaceutical products are expanding into the biotechnology field, and some pharmaceutical companies and generics manufacturers have formed partnerships to pursue biosimilars. In addition, some of our competitors may have technical, competitive or other advantages over us for the development of technologies and processes or greater experience in particular therapeutic areas, and consolidation among pharmaceutical and biotechnology companies can enhance such advantages. These advantages may make it difficult for us to compete with them to successfully discover, develop and market new products and for our current products to compete with new products or new product indications they may bring to market. As a result, our products may compete against products that offer higher rebates or discounts, lower prices, equivalent or superior performance, better safety profiles, easier administration, earlier market availability or other competitive features. If we are unable to compete effectively, this could reduce sales, which could have a material adverse effect on our business and results of operations.

Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in present and future intellectual property litigation.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. Driven by cost pressures, efforts to limit or weaken patent protection for our industry are increasing. Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. Challenges to patents may come from potential competitors or from parties other than those who seek to market a potentially-infringing product. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We have been in the past, and are currently and expect to be in the future, involved in patent litigation. These matters have included and may in the future include litigation with manufacturers of products that purport to be biosimilars of certain of our products for patent infringement and for failure to comply with certain provisions of the Biologics Price Competition and Innovation Act. A determination made by a court, agency or tribunal concerning infringement, validity, enforceability, injunctive or economic remedy, or the right to patent protection, for example, are typically subject to appellate or administrative review. Upon review, such initial determinations may be afforded little or no deference by the reviewing tribunal and may be affirmed, reversed, or made the subject of reconsideration through further proceedings. A patent dispute or litigation may not discourage a potential violator from bringing the allegedly-infringing product to market prior to a final resolution of the dispute or litigation. The period from inception until resolution of a patent dispute or litigation is subject to the availability and schedule of the court, agency or tribunal before which the dispute or litigation is pending. We may be subject to competition during this period and may not be able to recover fully from the losses, damages, and harms we incur from infringement by the competitor product even if we prevail. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities, be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Further, under the Hatch-Waxman Act, our products approved by the FDA under the FDCA may be the subject of patent litigation with generics competitors before expiry of the five-year period of data exclusivity provided for under the Hatch-Waxman Act and prior to the expiration of the patents listed for the product. Likewise, our innovative biologic products may be the subject of patent litigation prior to the expiration of our patents and, with respect to competitors seeking approval as a biosimilar or interchangeable version of our products, prior to the 12-year exclusivity period provided under the ACA. In addition, we are facing patent litigation involving claims that the biosimilar product candidates we are working to develop infringe the patents of other companies that manufacture,

market or sell the applicable reference products. For example, we are currently engaged in litigation in the United States regarding MVASI™, KANJINTI™ and AMJEVITA™, and in Europe we are engaged in litigation regarding AMGEVITA™. While we may attempt to challenge the patents held by the companies manufacturing, marketing or selling the applicable reference products, our efforts may be unsuccessful. Alternatively, such patents may contribute to a decision by us to not pursue all of the same labeled indications as are held by these companies. For information related to our patent litigation, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

Certain of the existing patents on our products have expired. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents. As our patents expire, competitors are able to legally produce and market similar products or technologies, including biosimilars, which may have a material adverse effect on our product sales, business and results of operations. In addition, competitors may be able to invalidate, design around or otherwise circumvent our patents and sell competing products.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. Professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities. Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies. In addition, a growing number of organizations are providing assessments of the value and pricing of biopharmaceutical products, and even organizations whose guidelines have historically been focused on clinical matters have begun to incorporate analyses of the cost effectiveness of various treatments into their treatment guidelines and recommendations. Value assessments may come from private organizations that publish their findings and offer recommendations relating to the products' reimbursement by government and private payers. Some companies and payers have announced pricing and payment decisions based in part on the assessments of private organizations. For example, CVS Caremark indicated in August 2018 that it will begin utilizing third-party cost effectiveness analyses to make formulary and coverage determinations for newly-approved drugs. In addition, government health technology assessment organizations in many countries make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service impact of new, emerging and existing medicines and treatments. Such health technology assessment organizations may recommend reimbursement for our product for a narrower indication than was approved by applicable regulatory agencies or may recommend against reimbursement entirely. Such recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could have a material adverse effect on our product sales, business and results of operations. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price of our common stock.

Our current products and products in development cannot be sold without regulatory approval.

Our business is subject to extensive regulation by numerous state and federal government authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in foreign countries to obtain approval from regulatory authorities before we manufacture, market and sell our products. Once our products are approved, the FDA and other U.S. and foreign regulatory agencies have substantial authority to require additional testing and reporting, perform inspections, change product labeling or mandate withdrawals of our products. Failure to comply with applicable regulatory requirements may subject us to administrative and/or judicially imposed sanctions or monetary penalties as well as reputational and other harms. The sanctions could include the FDA's or foreign regulatory authorities' refusals to approve pending applications, delays in obtaining or withdrawals of approvals, delays or suspensions of clinical trials, warning letters, product recalls or seizures, total or partial suspensions of our operations, injunctions, fines, civil penalties and/or criminal prosecutions.

Obtaining and maintaining regulatory approvals have been, and will continue to be, increasingly difficult, time-consuming and costly. Legislative bodies or regulatory agencies could enact new laws or regulations, change existing laws or regulations, or change their interpretations of laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products or product candidates. The rate and degree of change in existing laws and regulations and regulatory expectations have accelerated in established markets, and regulatory expectations continue to evolve in emerging markets. We are unable to predict whether and when any further changes to laws or regulatory policies affecting our business could occur, such as changes to laws or regulations governing manufacturer communications concerning drug products and drug product candidates, and whether such changes could have a material adverse effect on our product sales, business and results of operations. In the United States, a partial federal government shutdown halted the work of many federal agencies and their employees from late December 2018 through late January 2019. While federal employees have since returned to work, a subsequent extended shutdown could result in reductions or delays of FDA's activities, including with respect to our ongoing clinical programs, our manufacturing of our products and product candidates, and our product approvals.

Regulatory authorities may also question the sufficiency for approval of the endpoints we select for our clinical trials. A number of our products and product candidates have been evaluated in clinical trials using surrogate endpoints that measure an effect that is known to correlate with an ultimate clinical endpoint. For example, a

therapeutic oncology product candidate may be evaluated for its ability to extend the length of time during and after the treatment that a patient lives without the disease worsening, measured by progression-free survival (PFS). Demonstrating that the product candidate produces a statistically significant improvement in PFS does not necessarily mean that the product candidate will show a statistically significant improvement in overall survival, or the time that the patients remain alive. In the cardiovascular setting, a heart disease therapeutic

candidate may be evaluated for its ability to reduce LDL-C levels, as elevated LDL-C level has been a surrogate endpoint for cardiovascular events such as death, heart attack and stroke. The use of surrogate endpoints such as PFS and LDL-C reduction, in the absence of other measures of clinical benefit, may not be sufficient for broad usage or approval even when such results are statistically significant. Regulatory authorities could also add new requirements, such as the completion of enrollment in a confirmatory study or the completion of an outcomes study or a meaningful portion of an outcomes study, as conditions for obtaining approval or obtaining an indication. For example, our initial FDA application for Repatha® sought approval for a broader patient population based on data demonstrating that Repatha® reduced LDL-C levels. However, the FDA initially approved Repatha® in 2015 only for a subset of those patients, citing among other things the absence of positive outcomes data showing that Repatha® prevents cardiovascular events. In December 2017, the FDA granted broader approval of Repatha® to reduce the risk of certain cardiovascular events, and also to be used, alone or in combination with other lipid-lowering therapies, for the treatment of adults with primary hyperlipidemia to reduce LDL-C, only after our large phase 3 outcomes study evaluating the ability of Repatha® to prevent cardiovascular events met its primary composite endpoint and key secondary composite endpoint. There may also be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to other existing treatment options can be shown. The imposition of additional requirements or our inability to meet them in a timely fashion or at all may delay our clinical development and regulatory filing efforts, delay or prevent us from obtaining regulatory approval for new product candidates or new indications for existing products, or prevent us from maintaining our current labels.

Some of our products have been approved by U.S. and foreign regulatory authorities on an accelerated or conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, in March 2018, we announced that the FDA approved BLINCYTO® under accelerated approval for the treatment of adults and children with B-cell precursor ALL in first or second complete remission with minimal residual disease greater than or equal to 0.1 percent. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Regulatory authorities are placing greater focus on monitoring products originally approved on an accelerated or conditional basis and on whether the sponsors of such products have met the conditions of the accelerated or conditional approvals. If we are unable to fulfill the regulators' requirements that were conditions of a product's accelerated or conditional approval and/or if regulators re-evaluate the data or risk-benefit profile of our product, the conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change the product's labeled indications or even withdraw the product from the market.

Safety problems or signals can arise as our products and product candidates are evaluated in clinical trials, including investigator sponsored studies, or as our marketed products are used in clinical practice. We are required to continuously collect and assess adverse events reported to us and to communicate to regulatory agencies these adverse events and safety signals regarding our products. Regulatory agencies periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. In the United States, for our products with approved REMS (see Item 1. Business—Government Regulation—Post-approval Phase), we are required to submit periodic assessment reports to the FDA to demonstrate that the goals of the REMS are being met. REMS and other risk management programs are designed to ensure that a drug's benefits outweigh the risks, and vary in the elements they contain. If the FDA is not satisfied with the results of the periodic assessment reports we submit for any of our REMS, the FDA may also modify our REMS or take other regulatory actions, such as implementing revised or restrictive labeling. The drug delivery devices approved for use in combination with our products are also subject to regulatory oversight and review for safety and malfunctions. If regulatory agencies determine that we or other parties (including our clinical trial investigators, those operating our patient support programs or licensees of our products) have not complied with the applicable reporting, other pharmacovigilance or other safety or quality assessment requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including fines, marketing authorization withdrawal and other penalties. Our product candidates and marketed products can also be affected by safety problems or signals occurring with respect to products that are similar to ours or that implicate an entire class of products. Further, as a result of clinical trials, including sub-analyses or meta-analyses of earlier clinical trials (a meta-analysis involves the use of various statistical methods to combine results from previous separate but related studies) performed by us or others, concerns may arise about the sufficiency of the data or studies underlying a product's approved label. Such actual or perceived safety problems or concerns can lead to:

- revised or restrictive labeling for our products, or the potential for restrictive labeling that may result in our decision not to commercialize a product candidate;

- requirement of risk management activities or other regulatory agency compliance actions related to the promotion and sale of our products;

- mandated post-marketing commitments or pharmacovigilance programs for our approved products;

- product recalls of our approved products;

- required changes to the processes used in the manufacture of our products, which could increase our manufacturing costs and affect the availability of contract manufacturers we may utilize to assist in such manufacturing;

- revocation of approval for our products from the market completely, or within particular therapeutic areas or patient types;

- increased timelines or delays in being approved by the FDA or other regulatory bodies; and/or

- fewer treatments or product candidates being approved by regulatory bodies.

For example, the FDA is currently evaluating our BLA for EVENITY™ for the treatment of postmenopausal women with osteoporosis at high risk of fracture. In January 2018, the FDA's BRUDAC recommended that the FDA approve EVENITY™, but also suggested that the FDA require appropriate post-marketing review to evaluate a potential cardiovascular risk seen in one of the EVENITY™ pivotal clinical trials. See Item 1. Business—Significant Developments. While the FDA is not bound to follow the recommendations of its advisory committees, it often does; if the FDA approves EVENITY™ it may require that we complete a post-marketing study, which could be time consuming and costly.

In addition to our innovative products, we are working to develop and commercialize biosimilar versions of a number of products currently manufactured, marketed and sold by other pharmaceutical companies. In some markets, there is not yet a legislative or regulatory pathway for the approval of biosimilars. In the United States, the ACA provided for such a pathway; while the FDA continues to implement it, discussions continue as to the evidence needed to demonstrate biosimilarity or interchangeability for specific products. See *We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future.* Delays or uncertainties in the development or implementation of such pathways could result in delays or difficulties in getting our biosimilar products approved by regulatory authorities, subject us to unanticipated development costs or otherwise reduce the value of the investments we have made in the biosimilars area. Further, we cannot predict whether any repeal or reform of the ACA would affect the biosimilar pathway or have a material adverse effect on our development of biosimilars or on our marketed biosimilars. In addition, if we are unable to bring our biosimilar products to market on a timely basis, and secure "first-to-market" or other advantageous positions, our future biosimilar sales and results of operations could be materially and adversely affected.

We may not be able to develop commercial products despite significant investments in R&D.

Amgen invests heavily in R&D. Successful product development in the biotechnology industry is highly uncertain, and very few R&D projects produce commercial products. Product candidates, including biosimilar product candidates, or new indications for existing products (collectively, product candidates) that appear promising in the early phases of development may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results, for reasons that could include changes in the standard of care of medicine;

- the product candidate was not effective or not more effective than currently available therapies in treating a specified condition or illness;

- the product candidate was not cost effective in light of existing therapeutics;

- the product candidate had harmful side effects in animals or humans;

- the necessary regulatory bodies, such as the FDA or EMA, did not approve the product candidate for an intended use;

- the product candidate was not economical for us to manufacture and commercialize;

-

other parties had or may have had proprietary rights relating to our product candidate, such as patent rights, and did not let us sell it on reasonable terms, or at all;

- we and certain of our licensees, partners, contracted organizations or independent investigators may have failed to effectively conduct clinical development or clinical manufacturing activities;

- the pathway to regulatory approval or reimbursement for product candidates was uncertain or not well-defined; and

- the biosimilar product candidate failed to demonstrate the requisite biosimilarity to the applicable reference product, or was otherwise determined by a regulatory authority to not meet applicable standards for approval.

We have spent considerable time, energy and resources developing our expertise in human genetics with the belief that genetics could meaningfully aid our search for new medicines and help guide our research and development decisions and investments. We have focused our R&D strategy on drug targets validated by genetic or other compelling human evidence. However,

product candidates based on genetically validated targets remain subject to the uncertainties of the drug development process and may not reach the market for a number of reasons, including the factors listed above.

A number of our product candidates have failed or been discontinued at various stages in the product development process. For example, in May 2015, we terminated our participation in the co-development and commercialization of brodalumab with AstraZeneca. The decision was based on events of suicidal ideation and behavior in the brodalumab program, which we believed likely would necessitate restrictive labeling that would limit the appropriate patient population. Inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product for any of the reasons discussed could potentially have a negative impact on our product sales and earnings and could result in a significant impairment of in-process research and development (IPR&D) or other intangible assets.

We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.

Before we sell any products, we must conduct clinical trials to demonstrate that our product candidates are safe and effective for use in humans. The results of those clinical trials are used as the basis to obtain approval from regulatory authorities such as the FDA and EMA. See *Our current products and products in development cannot be sold without regulatory approval*. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims. The length of time, number of trial sites and number of patients required for clinical trials vary substantially, and we may spend several years and incur substantial expense in completing certain clinical trials. In addition, we may have difficulty finding a sufficient number of clinical trial sites and patients to participate in our clinical trials, particularly if competitors are conducting clinical trials in similar patient populations. Patients may withdraw from clinical trials at any time, and privacy laws and/or other restrictions in certain countries may restrict the ability of clinical trial investigators to conduct further follow-up on such patients, which may adversely affect the interpretation of study results. Delays and complications in planned clinical trials can result in increased development costs, associated delays in regulatory approvals and in product candidates reaching the market and revisions to existing product labels.

Further, to increase the number of patients available for enrollment in our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of locations where our experience conducting clinical trials is more limited, including Russia, India, China, South Korea, the Philippines, Singapore and some Central and South American countries, either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to understand the unique regulatory environments of individual countries. Further, we must ensure the timely production, distribution and delivery of the clinical supply of our product candidates to numerous and varied clinical trial sites. If we fail to adequately manage the design, execution and diverse regulatory aspects of our large and complex clinical trials or to manage the production or distribution of our clinical supply, corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates or could lose our ability to market existing products in certain therapeutic areas or altogether. If we are unable to market and sell our products or product candidates or to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations could be materially and adversely affected.

We rely on independent third-party clinical investigators to recruit patients and conduct clinical trials on our behalf in accordance with applicable study protocols, laws and regulations. Further, we rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations. In some circumstances, we enter into co-development arrangements with other pharmaceutical and medical devices companies that provide for the other company to conduct certain clinical trials for the product we are co-developing or to develop a diagnostic test used in screening patients for our clinical trials. See *Some of our pharmaceutical pipeline and of our commercial product sales relies on collaborations with third parties, which may adversely affect the development and sale of our products.* We also may acquire companies that have past or ongoing clinical trials or rights to products or product candidates for which clinical trials have been or are being conducted. These trials may not have been conducted to the same standards as ours; however, once an acquisition has been completed we assume responsibility for the conduct of these trials, including any potential risks and liabilities associated with the past and prospective conduct of those trials. If regulatory authorities determine that we or others, including our licensees or co-development partners, or the independent investigators or vendors selected by us, our co-development partners or by a company we have acquired or from which we have acquired rights to a product or product candidate, have not complied with regulations applicable to the clinical trials, those authorities may refuse or reject some or all of the clinical trial data or take other actions that could delay or otherwise negatively impact our ability to obtain or maintain marketing approval of the product or indication. In addition, delays or failures to develop diagnostic tests for our clinical trials

can affect the timely enrollment of such trials and lead to delays or inability to obtain marketing approval. If we were unable to market and sell our products or product candidates, our business and results of operations could be materially and adversely affected.

In addition, some of our clinical trials utilize drugs manufactured and marketed by other pharmaceutical companies. These drugs may be administered in clinical trials in combination with one of our products or product candidates or in a head-to-head

study comparing the products' or product candidates' relative efficacy and safety. In the event that any of these vendors or pharmaceutical companies have unforeseen issues that negatively impact the quality of their work product or create a shortage of supply, or if we are otherwise unable to obtain an adequate supply of these other drugs, our ability to complete our applicable clinical trials and/or evaluate clinical results may also be negatively impacted. As a result, such quality or supply problems could adversely affect our ability to timely file for, gain or maintain regulatory approvals worldwide.

Clinical trials must be designed based on the current standard of medical care. However, in certain diseases, such as cancer, the standard of care is evolving rapidly. In such diseases, the duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on standards of medical care that are no longer the current standards by the time such trials are completed, limiting the utility and application of such trials. We may not obtain favorable clinical trial results and therefore may not be able to obtain regulatory approval for new product candidates or new indications for existing products and/or maintain our current product labels. Participants in clinical trials of our products and product candidates may also suffer adverse medical events or side effects that could, among other factors, delay or terminate clinical trial programs and/or require additional or longer trials to gain approval.

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a risk management plan for our product or for approval of a new indication. For example, in connection with the June 2011 ESA label changes, we agreed to and conducted additional clinical trials examining the use of ESAs in CKD. Additional clinical trials we initiate, including those required by the FDA, could result in substantial additional expense and the outcomes could result in further label restrictions or the loss of regulatory approval for an approved indication, each of which could have a material adverse effect on our product sales, business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our products, our business and results of operations.

Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.

Many of our products and product candidates may be used in combination with a drug delivery device, such as an injector or other delivery system. For example, Neulasta® is available as part of the Neulasta® Onpro® kit, and our AutoTouch® reusable auto-injector is used with Enbrel Mini® single-dose prefilled cartridges. In addition, some of our products or product candidates may also require the use of a companion diagnostic device such as a device that determines whether the patient is eligible to use our drug or that helps ensure its safe and effective use. Our product candidates or expanded indications of our products used with such devices may not be approved or may be substantially delayed in receiving regulatory approval if development of such devices is delayed, such devices do not also gain or maintain regulatory approval or clearance, or if such devices do not remain commercially available. When approval of the product and device is sought under a single marketing drug application, the increased complexity of the review process may delay receipt of regulatory approval. In addition, some of these devices may be provided by single-source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or clearance by the applicable regulatory agencies. We are also dependent on those third-party companies continuing to meet applicable regulatory or other requirements. Failure to successfully develop, modify, or supply the devices, delays in or failures of the Amgen or third-party studies, or failure of us or the third-party companies to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs; delays in, or failure to obtain or maintain, regulatory approval; and/or associated delays in a product candidate reaching the market or in the addition of new indications for existing products. We are also required to collect and assess user complaints, adverse events, and malfunctions regarding our devices, and actual or perceived safety problems or concerns with a device used with our product can lead to regulatory actions and impacts to our products. See *Our current products and products in development cannot be sold without regulatory approval.* Additionally, regulatory agencies conduct routine monitoring and conduct inspections to identify and evaluate potential issues with our devices. For example, in 2017 the FDA reported on its adverse event reporting system that it is evaluating our Neulasta® Onpro® kit. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop, supply, or gain or maintain approval for these devices could adversely affect sales of the related, approved products.

Some of our pharmaceutical pipeline and of our commercial product sales relies on collaborations with third parties, which may adversely affect the development and sale of our products.

We depend on alliances with other companies, including pharmaceutical and biotechnology companies, vendors and service providers, for the development of a portion of the products in our pharmaceutical pipeline and for the

commercialization and sales of certain of our commercial products. For example, we have collaborations with third parties under which we share development rights, obligations and costs and/or commercial rights and obligations. See Item 1. Business—Business Relationships.

Failures by these parties to meet their contractual, regulatory, or other obligations to us, or any disruption in the relationships between us and these third parties, could have a material adverse effect on our pharmaceutical pipeline and business. In addition, our collaborative relationships for research and development and/or commercialization and sales often extend for many years and

may give rise to disputes regarding the relative rights, obligations and revenues of us and our collaboration partners, including the ownership or prosecution of intellectual property and associated rights and obligations. This could result in the loss of intellectual property rights or protection, delay the development and sale of potential pharmaceutical products, impact the effective sale and delivery of our commercialized products and lead to lengthy and expensive litigation, administrative proceedings or arbitration.

The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability.

We are subject to income and other taxes in the United States and other jurisdictions in which we do business. As a result, our provision for income taxes is derived from a combination of applicable tax rates in the various places we operate. Significant judgment is required for determining our provision for income tax.

Our tax returns are routinely examined by tax authorities in the United States and other jurisdictions in which we do business, and a number of audits are currently underway. Tax authorities, including the Internal Revenue Service (IRS), are becoming more aggressive in their audits and are particularly focused on the allocations of income and expense among tax jurisdictions. As previously disclosed, we received a Revenue Agent Report (RAR) from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Although final resolution of this complex matter is not likely within the next 12 months, such resolution could have a material negative impact on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued.

Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities, and changes in applicable tax laws, regulations or administrative interpretations thereof. The 2017 Tax Act is complex and further regulations and interpretations are still being issued. We could face audit challenges on how we apply the new law that could have a negative impact on our provision for income taxes. A change to the U.S. tax system, such as a repeal or modification of the 2017 Tax Act, a change to the tax system in a jurisdiction where we have significant operations, such as the U.S. territory of Puerto Rico, or changes in tax law in the United States or other jurisdictions where we do business, could have a material and adverse effect on our business and on the results of our operations.

We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.

The global supply of our products and product candidates for commercial sales and for use in our clinical trials is significantly dependent on the uninterrupted and efficient operation of our manufacturing facilities, in particular those in the U.S. territory of Puerto Rico and Thousand Oaks, California. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales*.

We currently perform a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California. A substantial disruption in our ability to operate our Thousand Oaks, California manufacturing facility could materially and adversely affect our ability to supply our product candidates for use in our clinical trials, leading to delays in development of our product candidates.

In addition, we currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico. In late September 2017, Hurricane Maria made landfall on the island of Puerto Rico. The hurricane destroyed residential and commercial buildings, agriculture, communications networks and most of Puerto Rico's electric grid. While the critical manufacturing areas of our commercial manufacturing facility were not significantly impacted by the storm, the restoration of electrical service on the island was a slow process, and our facility operated with electrical power from back-up diesel powered generators for some time. In January 2018, we reconnected to the Puerto Rico electric grid but have continued to use diesel generators as needed

when sufficient electric power has not been reliably available. Further instability of the electric grid could require us to increase the use of our generators or even return to using them exclusively. In addition, future storms or other disasters or events could cause a more significant impact to our manufacturing operations. A substantial disruption in our ability to operate our Puerto Rico manufacturing facility (whether due to problems with the facility itself, the infrastructure and services available on the island, the unavailability of raw materials or supplies from vendors, the unavailability of key staff or otherwise) or get supplies and manufactured products transported to and from that location could materially and adversely affect

our ability to supply our products and affect our product sales. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales*.

The impact of Hurricane Maria placed greater stress on the island's already challenged economy. Prior to Hurricane Maria, the government of Puerto Rico was unable to pay its roughly $72 billion in debt. In June 2016, the U.S. Congress passed the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA), which established a Financial Oversight and Management Board (Oversight Board) to provide fiscal oversight through the development and approval of fiscal plans and budgets for Puerto Rico and to assist in its debt restructuring. In May 2017, after negotiations for debt restructuring with creditors were unsuccessful, the Oversight Board approved and certified the filing in the U.S. District Court for the District of Puerto Rico of a voluntary petition under Title III of PROMESA for the government of Puerto Rico and certain of its governmental entities, including the Puerto Rico Electric Power Authority (PREPA). Title III of PROMESA provides Puerto Rico with a judicial process for restructuring its debt similar to, but not identical to, Chapter 9 of the U.S. Bankruptcy Code. The Governor of Puerto Rico declared a state of emergency and authorized a moratorium on the payment of general obligation bonds and other debts issued by certain instrumentalities, which moratorium has been extended and may continue to be extended while the Oversight Board is in effect. Given the severe conditions in Puerto Rico after Hurricane Maria, resolution of Puerto Rico's debt situation through the PROMESA judicial process has been delayed. In the case of PREPA, the effects of Hurricane Maria and several changes in PREPA's management have delayed reconstruction efforts.

In June 2018, the Oversight Board certified a budget for Puerto Rico's fiscal year 2019 that imposes significant expense reductions across the government. The Title III Court upheld government challenges to the budget, and the Governor and Legislature of Puerto Rico have now filed appeals before the U.S. Court of Appeals for the First Circuit. In addition, certain non-governmental entities have brought suit claiming the appointment process of the Oversight Board members set forth in PROMESA conflicts with the appointments clause of the U.S. Constitution. If the First Circuit were to hold that PROMESA has a constitutional infirmity and that actions taken by the Oversight Board are invalid, the commencement of all Title III proceedings could be invalid. In such event, the current debt restructuring process and the debtholder litigation stay under Title III of PROMESA could be in jeopardy.

In October 2018, the fiscal plan for Puerto Rico was updated, including a projected increase in federal disaster funding and projected material deficits once the stimulus effects of the disaster recovery dissipate. The fiscal plan stresses the importance of structural reforms to address Puerto Rico's challenging economic and demographic trends that may be difficult to implement as well as have a material adverse impact on our consolidated financial statements.

In addition, the 2017 Tax Act will no longer permit deferral of U.S. taxation on Puerto Rico earnings of U.S. companies (or their foreign subsidiaries), although these earnings generally will be taxed in the United States at a reduced 10.5% rate. Given Puerto Rico's challenged economy and hurricane recovery needs, it may be difficult for Puerto Rico to sustain or grow its manufacturing base due to competition from other foreign locations subject to a similar level of U.S. taxation, or U.S. locations due to the reduction in the U.S. corporate tax rate from 35% to 21%. The manufacturing sector contributes more than 45% of Puerto Rico's gross domestic product, and multinational companies with Puerto Rico operations contribute approximately 30% of Puerto Rico's revenue base.

While PROMESA and the actions above continue to be important factors in moving Puerto Rico toward economic stability, there is still a risk that Puerto Rico's ongoing economic challenges, the effects of Hurricane Maria and the potential impact of the 2017 Tax Act could negatively affect the territorial government's provision of utilities or other services in Puerto Rico that we use in the operation of our business, create the potential for increased taxes or fees to operate in Puerto Rico, result in a migration of workers from Puerto Rico to the mainland United States, or make it more expensive or difficult for us to operate in Puerto Rico, which could materially and adversely affect our ability to supply our products and affect our product sales.

We rely on third-party suppliers for certain of our raw materials, medical devices and components.

We rely on unaffiliated third-party suppliers for certain raw materials, medical devices and components necessary for the manufacturing of our commercial and clinical products. Certain of those raw materials, medical devices and components are proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug applications with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until the regulatory agency approved such supplier. For example, Insulet Corporation is our single-source of the on-body injector for our Neulasta® Onpro® kit. Also, certain of the raw materials required in the commercial and clinical manufacturing of our products are sourced

from other countries and/or derived from biological sources, including mammalian tissues, bovine serum and human serum albumin.

Among the reasons we may be unable to obtain these raw materials, medical devices and components include:

- regulatory requirements or action by regulatory agencies or others;
- adverse financial or other strategic developments at or affecting the supplier, including bankruptcy;

- unexpected demand for or shortage of raw materials, medical devices or components;
- failure to comply with our quality standards which results in quality and product failures, product contamination and/or recall;
- a material shortage, contamination, recall and/or restrictions on the use of certain biologically derived substances or other raw materials;
- discovery of previously unknown or undetected imperfections in raw materials, medical devices or components; and
- labor disputes or shortages, including from the effects of health emergencies and natural disasters.

For example, in prior years we have experienced shortages in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility. Further quality issues that result in unexpected additional demand for certain components may lead to shortages of required raw materials or components (such as we have experienced with EPOGEN® glass vials). We may experience similar or other shortages in the future resulting in delayed shipments, supply constraints, clinical trial delays, contract disputes and/or stock-outs of our products. These or other similar events could negatively impact our ability to satisfy demand for our products or conduct clinical trials, which could have a material adverse effect on our product sales, business and results of operations.

Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. We currently are involved in the manufacture of many of our products and plan to manufacture many of our product candidates. In addition, we currently use third-party contract manufacturers to produce, or assist in the production of, a number of our products, and we currently use contract manufacturers to produce, or assist in the production of, a number of our late-stage product candidates and drug delivery devices. See Item 1. Business—Manufacturing, Distribution and Raw Materials—Manufacturing. Our ability to adequately and timely manufacture and supply our products (and product candidates to support our clinical trials) is dependent on the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers, which may be impacted by:

- capacity of manufacturing facilities;
- contamination by microorganisms or viruses, or foreign particles from the manufacturing process;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of health emergencies or natural disasters;
- compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs and production success rates and yields;
- updates of manufacturing specifications;
- contractual disputes with our suppliers and contract manufacturers;
- timing and outcome of product quality testing;
- power failures and/or other utility failures;

- breakdown, failure, substandard performance or improper installation or operation of equipment; and/or

- delays in the ability of the FDA or foreign regulatory agencies to provide us necessary reviews, inspections and approvals, including as a result of a subsequent extended U.S. federal government shutdown.

If any of these or other problems affect production in one or more of our facilities or those of our third-party contract manufacturers, or if we do not accurately forecast demand for our products or the amount of our product candidates required in clinical trials, we may be unable to increase production in our unaffected facilities to meet demand. If the efficient manufacture and supply of our products or product candidates is interrupted, we may experience delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends, contract disputes and/or recalls of our products. From time to time we have initiated recalls of certain lots of our products. For example, in July 2014 we initiated a voluntary recall of an Aranesp® lot distributed in the EU after particles were detected in a quality control sample following distribution of that lot, and in April 2018 we initiated a precautionary recall of two batches of Vectibix® distributed in Switzerland after potential crimping defects were discovered in the metal seals on the product vials. If we are at any time unable to provide an uninterrupted supply of our products to patients,

we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could have a material adverse effect on our product sales, business and results of operations.

Our manufacturing processes, those of our third-party contract manufacturers and those of certain of our third-party service providers must undergo regulatory approval processes and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build, validate and license another manufacturing plant and it can take longer than three years to qualify and license a new contract manufacturer or service provider. If we elect or are required to make changes to our manufacturing processes because of new regulatory requirements, new interpretations of existing requirements or other reasons, this could increase our manufacturing costs and result in delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends or contract negotiations or disputes. Such manufacturing challenges may also occur if our existing contract manufacturers are unable or unwilling to implement such changes.

If regulatory authorities determine that we or our third-party contract manufacturers or certain of our third-party service providers have violated regulations or if authorities restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. Such issues may also delay the approval of product candidates we have submitted for regulatory review, even if such product candidates are not directly related to the products, devices or processes at issue with regulators. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis or at all. If we or our third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers fail to supply materials, products or services to us, we may experience delayed shipments, delays in our clinical trials, supply constraints, contract disputes, stock-outs and/or recalls of our products. Additionally, we distribute a substantial volume of our commercial products through our primary distribution centers in Louisville, Kentucky for the United States and in Breda, Netherlands for Europe and much of the rest of the world. We also conduct all the labeling and packaging of our products distributed in Europe and much of the rest of the world in Breda. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics centers, our third-party logistics providers and our labeling and packaging facility in Breda. Further, we rely on commercial transportation, including air and sea freight, for the distribution of our products to our customers, which may be negatively impacted by natural disasters or security threats.

Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively impact our business.

Certain of our distributors, customers and payers have substantial purchasing leverage, due to the volume of our products they purchase or the number of patient lives for which they provide coverage. The substantial majority of our U.S. product sales is made to three pharmaceutical product wholesaler distributors: AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc. These distributors, in turn, sell our products to their customers, which include physicians or their clinics, dialysis centers, hospitals and pharmacies. One of our products, EPOGEN®, is sold primarily to free-standing dialysis clinics. DaVita owns or manages a large number of the outpatient dialysis facilities located in the United States and accounts for approximately 70% of all EPOGEN® sales. Similarly, as discussed above, there has been significant consolidation in the health insurance industry, including that a small number of PBMs now oversee a substantial percentage of total covered lives in the United States. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability*. The three largest PBMs in the United States are now part of major health insurance providers. The growing concentration of purchasing and negotiating power by these entities may put pressure on our pricing due to their ability to extract price discounts on our products, fees for other services or rebates, negatively impacting our bargaining position, sales and/or profit margins. In addition, decisions by these entities to purchase or cover less or none of our products in favor of competitive products could have a material adverse effect on our product sales, business and results of operations due to their purchasing volume. Further, if one of our significant wholesale distributors encounters financial or other difficulties and becomes unable or unwilling to pay us all amounts that such distributor owes us on a timely basis or at all, it could negatively impact our business and results of operations. In addition, if one of our significant wholesale distributors becomes insolvent or otherwise unable to continue its commercial relationship with us in its present form, it could significantly disrupt our business and adversely affect our product sales, our business and results of operations unless suitable alternatives are timely found or lost sales are absorbed by another distributor.

Our efforts to acquire other companies or products and to integrate their operations may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.

We seek innovation through significant investment in both internal R&D and external transactions including collaborations, partnering, alliances, licenses, joint ventures, mergers and acquisitions (acquisition activity). We have an ongoing process of evaluating such potential acquisition activity opportunities that we expect will contribute to our future growth and expand our geographic footprint, product offerings and/or our R&D pipeline. Acquisitions or similar arrangements may be complex, time

consuming and expensive and may result in unanticipated costs, delays or other operational or financial problems related to integrating the acquired company and business with our company, which may result in the diversion of our management's attention from other business issues and opportunities. We may pay substantial amounts of cash, incur debt or issue equity securities to pay for acquisition activities, which could adversely affect our liquidity or result in dilution to our stockholders, respectively. Failures or difficulties in integrating or retaining new personnel or in integrating the operations of the businesses we acquire (including their technology, compliance programs, distribution and general business operations and procedures), while preserving important R&D, distribution, marketing, promotion and other relationships, may affect our ability to grow and may result in our incurring asset impairment or restructuring charges.

Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.

As we continue our expansion efforts in emerging markets around the world, through acquisitions and licensing transactions as well as through the development and introduction of our products in new markets, we face numerous risks to our business. There is no guarantee that our efforts and strategies to expand sales in emerging markets will succeed. Emerging market countries may be especially vulnerable to periods of global and local political, legal, regulatory and financial instability, including sovereign debt issues and/or the imposition of international sanctions in response to certain state actions. We may also be required to increase our reliance on third-party agents and unfamiliar operations and arrangements previously utilized by companies we partner with or acquire in emerging markets. See *We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications*. As we expand internationally, we are subject to fluctuations in foreign currency exchange rates relative to the U.S. dollar. While we have a program in place that is designed to reduce our exposure to foreign currency exchange rate fluctuations through foreign currency hedging arrangements, our hedging efforts do not completely offset the effect of these fluctuations on our revenues and earnings. Our international operations and business may also be subject to less protective intellectual property or other applicable laws, diverse data privacy and protection requirements, changing tax laws and tariffs, trade restrictions or other barriers designed to protect industry in the home country against foreign competition, far-reaching anti-bribery and anti-corruption laws and regulations and/or evolving legal and regulatory environments. These legal and operational challenges along with government controls, the challenges of attracting and retaining qualified personnel and obtaining and/or maintaining necessary regulatory or pricing approvals of our products may result in a material adverse impact on our international product sales, business and results of operations.

Our business may be affected by litigation and government investigations.

We and certain of our subsidiaries are involved in legal proceedings. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements. Civil and criminal litigation is inherently unpredictable, and the outcome can result in costly verdicts, fines and penalties, exclusion from federal healthcare programs and/or injunctive relief that affect how we operate our business. Defense of litigation claims can be expensive, time consuming and distracting, and it is possible that we could incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our product sales, business and results of operations. In addition, product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention and could adversely affect our reputation and the demand for our products. We and certain of our subsidiaries have previously been named as defendants in product liability actions for certain of our products.

We are also involved in government investigations that arise in the ordinary course of our business. In recent years, there has been a trend of increasing government investigations and litigations against companies operating in our industry, both in the United States and around the world. Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. We cannot ensure that all our employees, agents, contractors, vendors, licensees, partners or collaborators will comply with all applicable laws and regulations. In 2012, we finalized a settlement agreement with the U.S. government and various other parties to settle certain allegations regarding our sales and marketing practices and agreed to operate under a corporate integrity agreement with the OIG of the U.S. Department of Health and Human Services, which was formally closed out in August 2018. We may see new government investigations of or actions against us citing novel theories of recovery. Any of these results could have a material adverse effect on our business and results of operations.

A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems and network-connected control systems and our data, interrupt the operation of our business and affect our reputation.

To achieve our business objectives, we rely to a large extent upon sophisticated information technology systems and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or affect our reputation.

Our information technology systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. The complexity and interconnected nature of our systems makes them potentially vulnerable to breakdown or other service interruptions. Our systems are also subject to frequent cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering and/or other means. Attacks such as those seen with other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access important data needed to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and distributing our products. For example, in 2017, a pharmaceutical company experienced a cyberattack involving virulent malware that significantly disrupted its operations, including its research and sales operations and the production of some of its medicines and vaccines. As a result of the cyberattack, its orders and sales for certain products in certain markets were negatively impacted. Our systems also contain and utilize a high volume of sensitive data, including intellectual property, trade secrets, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials or personal information belonging to us, our staff, our patients, customers and/or other business partners. In some cases, we utilize third-party service providers to process, store, manage or transmit such data, which may increase our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) by employees, service providers, nation states, organized crime organizations, "hacktivists" or others, pose risks that our sensitive data may be exposed to unauthorized persons, our competitors, or the public. Finally, domestic and global government regulators, our key business partners, suppliers with whom we do business, companies that provide us or our partners with important business services and companies we may acquire may face similar risks, and security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. For example, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers.

Although in the past we have experienced system breakdowns, attacks and information security breaches, we do not believe such breakdowns, attacks and breaches have had a material adverse effect on our business or results of operations. We continue to invest in the monitoring, protection, and resilience of our critical or sensitive data and systems. However, there can be no assurance that our efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks, or breaches of our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data, which could result in financial, legal, business or reputational harm to us or impact our stock price. While we maintain cyber-liability insurance, our insurance is not sufficient to cover us against all losses that could potentially result from a service interruption, breach of our systems or loss of our critical or sensitive data.

Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Our operations and performance have been, and may continue to be, affected by global economic conditions. Financial pressures may cause government or other third-party payers to more aggressively seek cost containment measures. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability*. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships may also affect patients' ability to afford health care as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to reduced demand for our products, which could have a material adverse effect on our product sales, business and results of operations. Economic conditions may also adversely affect the ability of our distributors, customers and suppliers to obtain the liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Although we monitor our distributors', customers' and suppliers' financial condition and their liquidity to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could have a material adverse effect on our product sales, business and results of operations.

We maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our consolidated balance sheets. The value of our investments may be adversely affected by interest rate fluctuations, downgrades in credit ratings, illiquidity in the capital markets and other factors that may result in other-than-temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on sales of investments.

Our stock price is volatile.

Our stock price, like that of our peers in the biotechnology and pharmaceutical industries, is volatile. Our revenues and operating results may fluctuate from period to period for a number of reasons. Events such as a delay in product development, changes to our expectations or strategy or even a relatively small revenue shortfall may cause financial results for a period to be

below our expectations or projections. As a result, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Announcements or discussions, including via social media channels, of possible restrictive actions by government or private payers that would impact our business or industry if ultimately enacted or adopted may also cause our stock price to fluctuate, whether or not such restrictive actions ever actually occur. Similarly, actual or perceived safety issues with our products or similar products or unexpected clinical trial results can have an immediate and rapid impact on our stock price, whether or not our operating results are materially impacted.

We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The capital and credit markets may experience extreme volatility and disruption which may lead to uncertainty and liquidity issues for both borrowers and investors. We expect to access the capital markets to supplement our existing funds and cash generated from operations in satisfying our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. In the event of adverse capital and credit market conditions, we may be unable to obtain capital market financing on similar favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Changes in credit ratings issued by nationally recognized credit-rating agencies could adversely affect our ability to obtain capital market financing and the cost of such financing and have an adverse effect on the market price of our securities.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

As of December 31, 2018, we owned or leased approximately 190 properties. The locations and primary functions of significant properties are summarized in the following tables:

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Excluded from the information above are (i) undeveloped land and leased properties that have been abandoned and (ii) certain buildings that we still own but are no longer used in our business. There are no material encumbrances on our owned properties.

We believe that our facilities are suitable for their intended uses and, in conjunction with our third-party contracting manufacturing agreements, provide adequate capacity and are sufficient to meet our expected needs. See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

See Item 1. Business—Manufacturing, Distribution and Raw Materials.

Item 3. LEGAL PROCEEDINGS

Certain of the legal proceedings in which we are involved are discussed in Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements, and are hereby incorporated by reference.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Common stock

Our common stock trades on the NASDAQ Global Select Market under the symbol AMGN. As of February 7, 2019, there were approximately 5,760 holders of record of our common stock.

Performance graph

The following graph shows the value of an investment of $100 on December 31, 2013, in each of Amgen common stock, the Amex Biotech Index, the Amex Pharmaceutical Index and Standard & Poor's 500 Index (S&P 500). All values assume reinvestment of the pretax value of dividends and are calculated as of December 31 of each year. The historical stock price performance of the Company's common stock shown in the performance graph is not necessarily indicative of future stock price performance.

Amgen vs. Amex Biotech, Amex Pharmaceutical and S&P 500 Indices

Comparison of Five-Year Cumulative Total Return

Value of Investment of $100 on December 31, 2013

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	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
Amgen (AMGN)	$100.00	$142.32	$147.97	$136.80	$167.33	$192.57
Amex Biotech (BTK)	$100.00	$147.91	$164.76	$133.21	$183.58	$184.07
Amex Pharmaceutical (DRG)	$100.00	$116.58	$121.45	$111.32	$129.83	$139.50
S&P 500 (SPX)	$100.00	$113.68	$115.24	$129.02	$157.26	$150.39

The material in this performance graph is not soliciting material, is not deemed filed with the SEC, and is not incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made on, before or after the date of this filing and irrespective of any general incorporation language in such filing.

Stock repurchase program

During the three months and year ended December 31, 2018, we had one outstanding stock repurchase program, under which the repurchasing activity was as follows:

	Total number of shares purchased	Average price paid per share[1]	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program[2]
October 1 - October 31	4,151,700	$ 198.37	4,151,700	$ 2,855,891,358
November 1 - November 30	2,461,000	$ 195.19	2,461,000	$ 2,375,524,842
December 1 - December 31	4,508,700	$ 190.99	4,508,700	$ 5,114,429,813
	11,121,400	$ 194.67	11,121,400	
January 1 - December 31	94,473,223	$ 189.00	94,473,223	

(1) Average price paid per share includes related expenses.

(2) In December 2018, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $3.6 billion.

Dividends

For the years ended December 31, 2018 and 2017, we paid quarterly dividends. We expect to continue to pay quarterly dividends, although the amount and timing of any future dividends are subject to approval by our Board of Directors. Additional information required by this item is incorporated herein by reference to Part IV—Note 17, Stockholders' equity, to the Consolidated Financial Statements.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

Information about securities authorized for issuance under existing equity compensation plans is incorporated by reference from Item 12—Securities Authorized for Issuance Under Existing Equity Compensation Plans.

Item 6. SELECTED FINANCIAL DATA

Consolidated Statements of Income Data:	Years ended December 31, 2018	2017	2016	2015	2014
	(In millions, except per-share data)				
Revenues:					
Product sales	$ 22,533	$ 21,795	$ 21,892	$ 20,944	$ 19,327
Other revenues	1,214	1,054	1,099	718	736
Total revenues	$ 23,747	$ 22,849	$ 22,991	$ 21,662	$ 20,063
Operating expenses:					
Cost of sales	$ 4,101	$ 4,069	$ 4,162	$ 4,227	$ 4,422
Research and development	$ 3,737	$ 3,562	$ 3,840	$ 4,070	$ 4,297
Selling, general and administrative	$ 5,332	$ 4,870	$ 5,062	$ 4,846	$ 4,699
Net income[1]	$ 8,394	$ 1,979	$ 7,722	$ 6,939	$ 5,158
Diluted earnings per share[1]	$ 12.62	$ 2.69	$ 10.24	$ 9.06	$ 6.70
Dividends paid per share	$ 5.28	$ 4.60	$ 4.00	$ 3.16	$ 2.44

Consolidated Balance Sheets Data:	As of December 31, 2018	2017	2016	2015	2014
	(In millions)				
Total assets	$ 66,416	$ 79,954	$ 77,626	$ 71,449	$ 68,882
Total debt[2]	$ 33,929	$ 35,342	$ 34,596	$ 31,429	$ 30,588
Total stockholders' equity[3]	$ 12,500	$ 25,241	$ 29,875	$ 28,083	$ 25,778

In addition to the following notes, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, Part IV—Consolidated Financial Statements and accompanying notes and previously filed Annual Reports on Form 10-K for further information regarding our consolidated results of operations and financial position for periods reported therein and for known factors that will affect the comparability of future results. Also see Part IV—Note 17, Stockholders' equity, to the Consolidated Financial Statements, for information regarding cash dividends declared per share of common stock for each of the four quarters of 2018, 2017 and 2016. In addition, our Board of Directors declared dividends per share of $0.79 and $0.61 that were paid in each of the four quarters of 2015 and 2014, respectively.

(1) In 2017, we recorded a net charge of $6.1 billion as a result of the 2017 Tax Act. See Part IV—Note 7, Income taxes, to the Consolidated Financial Statements.

(2) See Part IV—Note 16, Financing arrangements, to the Consolidated Financial Statements, for discussion of our financing arrangements. In 2015, we issued $3.5 billion of debt and repaid $2.4 billion of debt. In 2014, we issued $4.5 billion of debt and repaid $5.6 billion of debt.

(3) Throughout the five years ended December 31, 2018, we had a stock repurchase program authorized by the Board of Directors, through which we repurchased $17.9 billion, $3.1 billion, $3.0 billion, $1.9 billion and $0.2 billion, respectively, of Amgen common stock.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis (MD&A) is intended to assist the reader in understanding Amgen's business. MD&A is provided as a supplement to, and should be read in conjunction with, our consolidated financial statements and accompanying notes. Our results of operations discussed in MD&A are presented in conformity with U.S. generally accepted accounting principles (GAAP). Amgen operates in one business segment: human therapeutics. Therefore, our results of operations are discussed on a consolidated basis.

Forward-looking statements

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. In addition, we, or others on our behalf, may make forward-looking statements in press releases or written statements, or in our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Such words as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume," and "continue," as well as variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and they involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in Part I, Item 1A. Risk Factors. We have based our forward-looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecasted by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, earnings per share (EPS), liquidity and capital resources, trends, planned dividends, stock repurchases and restructuring plans. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

Amgen is a highly focused biotechnology company committed to unlocking the potential of biology for patients suffering from serious illnesses. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Our principal products—those with the most significant annual commercial sales—are ENBREL, Neulasta®, Prolia®, Aranesp®, XGEVA®, Sensipar®/Mimpara® and EPOGEN®. We also market a number of other products, including KYPROLIS®, Nplate®, Vectibix®, Repatha®, NEUPOGEN®, Parsabiv®, BLINCYTO®, Aimovig®, IMLYGIC®, Corlanor®, KANJINTI™ and AMGEVITA™. For additional information about our products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products.

Our strategy includes a set of integrated activities intended to maintain and strengthen our competitive position in the industry. In 2018, we advanced our strategy while delivering strong financial performance and returning capital to shareholders, advancing our innovative pipeline and branded biosimilar programs, increasing our global geographic reach and expanding our next-generation manufacturing capabilities.

In 2018, total product sales increased 3% driven primarily by Prolia®, XGEVA®, Repatha® and KYPROLIS®, along with our recently launched products Aimovig® and Parsabiv®. Product sales grew 2% in the United States and 9% in the rest of the world. Total operating expenses increased 5% as we supported our recently launched products and R&D pipeline, including early oncology assets. Cash inflows from operating activities were $11.3 billion, enabling us to invest in our business while returning capital to shareholders through the payment of cash dividends and stock repurchases. We increased our quarterly cash dividend by 15% to $1.32 per share of common stock. In December 2018, we declared a cash dividend of $1.45 per share of common stock for the first quarter of 2019, an increase of 10% for this period, to be paid in March 2019. We also repurchased 94.5 million shares of our common stock throughout 2018 at an aggregate cost of $17.9 billion.

In addition to launching Aimovig® in the United States and Parsabiv® in the United States and the EU, we received approvals for new indications for Repatha® and Prolia®, along with KYPROLIS®, BLINCYTO®, XGEVA® and Nplate® within our oncology/hematology portfolio. We continued to strengthen our international footprint with the approvals of Repatha® in China, and in early 2019, EVENITY™ in Japan. In addition to these commercial products, we continue to advance our pipeline of innovative first-in-class molecules, including our phase 3 molecule, tezepelumab. The FDA granted Breakthrough Therapy Designation for tezepelumab in patients with severe asthma without an eosinophilic phenotype. We have also continued to invest in external innovation to augment our internal innovation with a focus when possible, on genetic related investments and genetically validated targets.

We also continued to advance our biosimilar program with the approval of MVASI™ for the treatment of five types of cancer in the United States and the EU, and the launches of KANJINTI™ and AMGEVITA™ in Europe. Lastly, we made regulatory submissions for ABP 710 in the United States and the EU.

We broke ground on our new next-generation biomanufacturing plant in Rhode Island in 2018. This new plant will be the first of its kind in the United States and will use our proven next-generation biomanufacturing capabilities to manufacture our products while maintaining a reliable, high-quality, compliant supply of medicines. Next-generation biomanufacturing plants require a smaller manufacturing footprint and offer greater environmental benefits, including reduced consumption of water and energy and lower levels of carbon emissions. Our first next-generation biomanufacturing facility located in Singapore is already in use for certain commercial-scale production for multiple countries.

While 2018 execution was strong, we face competition on our more mature products. We have established productivity initiatives to enable investment in new products and the defense of existing products to optimize long- and short-term growth.

Our long-term success depends, to a great extent, on our ability to continue to discover, develop and commercialize innovative products and acquire or collaborate on therapies currently in development by other companies. We must develop new products over time in order to provide for revenue growth and to offset revenue losses when products lose their exclusivity or competing products are launched. Certain of our products face increasing pressure from competition, including biosimilars and generics. For additional information, including information on the expiration of patents for various products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents and see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We devote considerable resources to R&D activities. However, successful product

development in the biotechnology industry is highly uncertain. We are also confronted by increasing regulatory scrutiny of safety and efficacy both before and after products launch.

Rising healthcare costs and economic conditions also continue to pose challenges to our business, including continued pressure by third-party payers, such as governments and private payers, to reduce healthcare expenditures. As a result of public

and private health care provider focus, the industry continues to experience significant pricing pressures and other cost containment measures. Finally, wholesale and end-user buying patterns can affect our product sales. These effects can cause fluctuations in quarterly product sales and have generally not been significant when comparing full-year product performance to the prior year. See Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products and Part I, Item 1A. Risk Factors for further discussion of certain of the factors that could impact our future product sales.

Selected Financial Information

The following is an overview of our results of operations (in millions, except percentages and per-share data):

	Year ended December 31, 2018	Change	Year ended December 31, 2017
Product sales:			
U.S.	$ 17,429	2 %	$ 17,131
Rest of world (ROW)	5,104	9 %	4,664
Total product sales	22,533	3 %	21,795
Other revenues	1,214	15 %	1,054
Total revenues	$ 23,747	4 %	$ 22,849
Operating expenses	$ 13,484	5 %	$ 12,876
Operating income	$ 10,263	3 %	$ 9,973
Net income	$ 8,394	*	$ 1,979
Diluted EPS	$ 12.62	*	$ 2.69
Diluted shares	665	(10 %)	735

* Change in excess of 100%

In the following discussion of changes in product sales, any reference to unit demand growth or decline refers to changes in the purchases of our products by healthcare providers (such as physicians or their clinics), dialysis centers, hospitals and pharmacies. In addition, any reference to increases or decreases in inventory refers to changes in inventory held at wholesaler customers and end-users (such as pharmacies).

Total product sales increased for 2018, driven primarily by higher unit demand, offset partially by a decline in net selling price. For 2019, we expect net selling price to continue to decline.

Other revenues increased for 2018, driven primarily by higher milestone payments and royalties.

Operating expenses increased for 2018, driven primarily by investments in product launches and increased spend in R&D, including support of our early pipeline. All expense categories continued to benefit from our transformation and process improvement efforts, which enabled investment in newer and recently launched products.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is offset partially by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material in 2018, 2017 or 2016.

Results of Operations

Product sales

Worldwide product sales were as follows (dollar amounts in millions):

	Year ended December 31, 2018	Change	Year ended December 31, 2017	Change	Year ended December 31, 2016
ENBREL	$ 5,014	(8)%	$ 5,433	(9)%	$ 5,965
Neulasta®	4,475	(1)%	4,534	(2)%	4,648
Prolia®	2,291	16 %	1,968	20 %	1,635
Aranesp®	1,877	(9)%	2,053	(2)%	2,093
XGEVA®	1,786	13 %	1,575	3 %	1,529
Sensipar®/Mimpara®	1,774	3 %	1,718	9 %	1,582
EPOGEN®	1,010	(8)%	1,096	(15)%	1,282
Other products	4,306	26 %	3,418	8 %	3,158
Total product sales	$ 22,533	3 %	$ 21,795	— %	$ 21,892
Total U.S.	$ 17,429	2 %	$ 17,131	(1)%	$ 17,325
Total ROW	5,104	9 %	4,664	2 %	4,567
Total product sales	$ 22,533	3 %	$ 21,795	— %	$ 21,892

Future sales of our products will depend, in part, on the factors discussed in the Overview, Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition, in Part I, Item 1A. Risk Factors, and any additional factors discussed in the individual product sections below. In addition, for a list of our products' significant competitors, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition.

ENBREL

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2018	Change	Year ended December 31, 2017	Change	Year ended December 31, 2016
ENBREL — U.S.	$ 4,807	(8)%	$ 5,206	(9)%	$ 5,719
ENBREL — Canada	207	(9)%	227	(8)%	246
Total ENBREL	$ 5,014	(8)%	$ 5,433	(9)%	$ 5,965

The decrease in ENBREL sales for 2018 was driven primarily by lower unit demand and net selling price.

The decrease in ENBREL sales for 2017 was driven primarily by lower unit demand and net selling price, offset partially by an increase in inventory.

For 2019, we expect the trend of lower unit demand to continue.

Multiple companies are developing proposed biosimilar versions of ENBREL, and we are involved in patent litigation with the company seeking to market the biosimilar version of ENBREL approved by the FDA in 2016. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

Neulasta®

Total Neulasta® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2018	Change	Year ended December 31, 2017	Change	Year ended December 31, 2016
Neulasta® — U.S.	$ 3,866	(2)%	$ 3,931	— %	$ 3,925
Neulasta® — ROW	609	1 %	603	(17)%	723
Total Neulasta®	$ 4,475	(1)%	$ 4,534	(2)%	$ 4,648

The decrease in global Neulasta® sales for 2018 was driven primarily by favorable changes in accounting estimates of product returns in 2017, offset partially by favorable changes in inventory. Neulasta® sales for 2018 included a $55 million order in the fourth quarter from the U.S. government.

The decrease in global Neulasta® sales for 2017 was driven primarily by lower unit demand, offset partially by an increase in net selling price in the United States.

Neulasta® sales have been and will continue to be affected by the development of new protocols, tests and/or treatments for cancer and/or new treatment alternatives, including those that have reduced and may continue to reduce the use of myelosuppressive regimens in some patients.

Our final material U.S. patent for Neulasta® expired in October 2015. Therefore, we face competition in the United States, which over time may have a material adverse impact on future sales of Neulasta®. A biosimilar version of Neulasta® was approved in the second quarter of 2018 and launched in July 2018, and another biosimilar version was approved in the fourth quarter of 2018 and launched in January 2019. Other biosimilar versions of Neulasta® may also receive approval in the near future. For a discussion of ongoing patent litigations with these and other companies that are developing proposed biosimilar versions of Neulasta®, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

In addition, supplementary protection certificates issued by certain countries, including France, Germany, Italy, Spain and the United Kingdom, that are related to our European patent for Neulasta® expired in August 2017. In 2019, we expect European sales to decline with the launch of multiple long-acting biosimilar competitors.

Prolia®

Total Prolia® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2018	Change	Year ended December 31, 2017	Change	Year ended December 31, 2016
Prolia® — U.S.	$ 1,500	18 %	$ 1,272	21 %	$ 1,049
Prolia® — ROW	791	14 %	696	19 %	586
Total Prolia®	$ 2,291	16 %	$ 1,968	20 %	$ 1,635

The increases in global Prolia® sales for 2018 and 2017 were driven primarily by higher unit demand.

Aranesp®

Total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2018	Change	Year ended December 31, 2017	Change	Year ended December 31, 2016
Aranesp® — U.S.	$ 942	(15)%	$ 1,114	3 %	$ 1,082
Aranesp® — ROW	935	— %	939	(7)%	1,011

Total Aranesp®	$ 1,877	(9%)	$ 2,053	(2%)	$ 2,093

The decrease in global Aranesp® sales for 2018 was driven primarily by the impact of competition on unit demand.

The decrease in global Aranesp® sales for 2017 was driven primarily by unfavorable changes in foreign currency exchange rates, offset partially by higher unit demand, including a shift of some U.S. dialysis centers from EPOGEN®.

Aranesp® faces competition from a long-acting product. Aranesp® also faces competition from a biosimilar version of EPOGEN®, which was approved in the second quarter of 2018 and launched in the fourth quarter of 2018. Other biosimilar versions of EPOGEN ® may also receive approval. In 2019, we expect sales in the United States to decline at a faster rate than 2018 due to short- and long- acting competition.

XGEVA®

Total XGEVA® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2018	Change	Year ended December 31, 2017	Change	Year ended December 31, 2016
XGEVA® — U.S.	$ 1,338	16 %	$ 1,157	4 %	$ 1,115
XGEVA® — ROW	448	7 %	418	1 %	414
Total XGEVA®	$ 1,786	13 %	$ 1,575	3 %	$ 1,529

The increases in global XGEVA® sales for 2018 and 2017 were driven primarily by higher unit demand.

Sensipar®/Mimpara®

Total Sensipar®/Mimpara® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2018	Change	Year ended December 31, 2017	Change	Year ended December 31, 2016
Sensipar® — U.S.	$ 1,436	5 %	$ 1,374	11 %	$ 1,240
Sensipar®/Mimpara® — ROW	338	(2 %)	344	1 %	342
Total Sensipar®/Mimpara®	$ 1,774	3 %	$ 1,718	9 %	$ 1,582

The increase in global Sensipar®/Mimpara® sales for 2018 was driven primarily by an increase in net selling price in the United States, offset partially by lower unit demand.

The increase in global Sensipar®/Mimpara® sales for 2017 was driven primarily by an increase in net selling price in the United States and, to a lesser extent, higher unit demand.

Our U.S. composition of matter patent related to Sensipar®, a small molecule, expired in March 2018. We are involved in patent litigation with a number of companies seeking to market generic versions of Sensipar®, one of which began selling its generic version in late December 2018 until reaching a settlement agreement with us in early January 2019. In a separate litigation, we have been sued by the manufacturer of another approved generic version of Sensipar® who is contending that provisions of its own settlement agreement with Amgen have been triggered by the first manufacturer's at-risk launch, giving this second manufacturer a right to market its own generic version under its settlement agreement. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

In 2019, we expect Sensipar® sales will be lower than 2018 due to the temporary generic market entry, continued adoption of Parsabiv® and higher purchases in 2018 due to the reimbursement change from Medicare Part D to Part B. Further, generic competitors may enter the market at risk at any time.

EPOGEN®

Total EPOGEN® sales were as follows (dollar amounts in millions):

	Year ended December 31, 2018	Change	Year ended December 31, 2017	Change	Year ended December 31, 2016
EPOGEN® — U.S.	$ 1,010	(8 %)	$ 1,096	(15 %)	$ 1,282

The decrease in EPOGEN® sales for 2018 was driven primarily by a decline in net selling price due to contractual terms negotiated with DaVita (see Part I, Item I. Business—Business Relationships). In 2019, we expect a more significant decline in net selling price.

The decrease in EPOGEN® sales for 2017 was driven primarily by a decline in net selling price due to contractual terms negotiated with DaVita and, to a lesser extent, a shift in some U.S. dialysis centers to Aranesp®.

Our final material U.S. patent for EPOGEN® expired in May 2015. We face competition in the United States, which has had and will continue to have a material adverse impact on sales of EPOGEN ®. Multiple companies are developing proposed biosimilar versions of EPOGEN ®. A biosimilar version of EPOGEN ® was approved in the second quarter of 2018 and launched in the fourth quarter of 2018. Other biosimilar versions of EPOGEN ® may also receive approval. For a discussion of ongoing patent litigation with one of these companies, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

Other products

Other product sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2018	Change	Year ended December 31, 2017	Change	Year ended December 31, 2016
KYPROLIS® — U.S.	$ 583	4 %	$ 562	1 %	$ 554
KYPROLIS® — ROW	385	41 %	273	98 %	138
Nplate® — U.S.	438	12 %	392	12 %	350
Nplate® — ROW	279	12 %	250	7 %	234
Vectibix® — U.S.	288	15 %	251	10 %	229
Vectibix® — ROW	403	3 %	391	2 %	382
Repatha® — U.S.	358	59 %	225	*	101
Repatha® — ROW	192	*	94	*	40
NEUPOGEN® — U.S.	223	(40 %)	369	(31 %)	534
NEUPOGEN® — ROW	142	(21 %)	180	(22 %)	231
Parsabiv® — U.S.	302	*	—	— %	—
Parsabiv® — ROW	34	*	5	*	—
BLINCYTO® — U.S.	134	18 %	114	34 %	85
BLINCYTO® — ROW	96	57 %	61	*	30
Aimovig® — U.S.	119	*	—	— %	—
Biosimilars — ROW	55	*	—	— %	—
Other — U.S.	85	25 %	68	13 %	60
Other — ROW	190	4 %	183	(4 %)	190
Total other product sales	$ 4,306	26 %	$ 3,418	8 %	$ 3,158
Total U.S. — other products	$ 2,530		$ 1,981		$ 1,913
Total ROW — other products	1,776		1,437		1,245
Total other product sales	$ 4,306		$ 3,418		$ 3,158

* Change in excess of 100%

Operating expenses

Operating expenses were as follows (dollar amounts in millions):

	Year ended December 31, 2018	Change	Year ended December 31, 2017	Change	Year ended December 31, 2016
Operating expenses:					
Cost of sales	$ 4,101	1 %	$ 4,069	(2 %	$ 4,162
% of product sales	18.2 %		18.7 %		19.0 %
% of total revenues	17.3 %		17.8 %		18.1 %
Research and development	$ 3,737	5 %	$ 3,562	(7 %	$ 3,840
% of product sales	16.6 %		16.3 %		17.5 %
% of total revenues	15.7 %		15.6 %		16.7 %
Selling, general and administrative	$ 5,332	9 %	$ 4,870	(4 %	$ 5,062
% of product sales	23.7 %		22.3 %		23.1 %
% of total revenues	22.5 %		21.3 %		22.0 %
Other	$ 314	(16 %	$ 375	*	$ 133

* Change in excess of 100%

Transformation and process improvement

During 2014, we announced transformation and process improvement efforts that we continue to execute. As part of these efforts, we committed to a more agile and efficient operating model. Our transformation and process improvement efforts across the Company are enabling us to reallocate resources to fund many of our innovative pipeline and growth opportunities that deliver value to patients and stockholders.

The transformation included a restructuring plan, and the activities associated with the restructuring plan have been completed. As of December 31, 2018, restructuring costs incurred to date were $809 million. During 2018, 2017 and 2016, we incurred restructuring costs of $12 million, $88 million and $37 million, respectively. Since 2014, we have realized approximately $1.9 billion of transformation and process improvement savings. Net savings have not been significant as savings were reinvested in product launches, clinical programs and external business development. Additional information required for our restructuring plan is incorporated herein by reference to Part IV—Note 2, Restructuring, to the Consolidated Financial Statements.

Cost of sales

Cost of sales decreased to 17.3% of total revenues for 2018, driven primarily by lower royalty costs, expenses related to Hurricane Maria in 2017 and lower acquisition-related amortization of intangible assets, offset partially by higher manufacturing costs.

Cost of sales decreased to 17.8% of total revenues for 2017, driven primarily by lower acquisition-related amortization of intangible assets, lower royalty costs and favorable manufacturing costs, offset partially by expenses related to Hurricane Maria, unfavorable product mix and other inventory costs.

Research and development

The Company groups all of its R&D activities and related expenditures into three categories: (1) Research and early pipeline (formerly Discovery Research and Translational Sciences), (2) later-stage clinical programs and (3) marketed products. These categories are described below:

Category	Description
Research and early pipeline	R&D expenses incurred in activities substantially in support of early research through the completion of phase 1 clinical trials, including drug discovery, toxicology, pharmacokinetics and drug metabolism, and process development.
Later-stage clinical programs	R&D expenses incurred in or related to phase 2 and phase 3 clinical programs intended to result in registration of a new product or a new indication for an existing product in the United States or the EU.
Marketed products	R&D expenses incurred in support of the Company's marketed products that are authorized to be sold in the United States or the EU. Includes clinical trials designed to gather information on product safety (certain of which may be required by regulatory authorities) and their product characteristics after regulatory approval has been obtained, as well as the costs of obtaining regulatory approval of a product in a new market after approval in either the United States or the EU has been obtained.

R&D expense by category was as follows (in millions):

	Years ended December 31,		
	2018	2017	2016
Research and early pipeline	$ 1,201	$ 972	$ 1,039
Later-stage clinical programs	1,034	879	1,054
Marketed products	1,502	1,711	1,747
Total R&D expense	$ 3,737	$ 3,562	$ 3,840

The increase in R&D expense for 2018 was driven by higher spend on our early pipeline, later-stage clinical programs as well as external business development expense in research and early pipeline, offset partially by lower marketed product support.

The decrease in R&D expense for 2017 was driven by decreased costs associated with later-stage clinical program support, lower external business development expense in research and early pipeline and lower marketed product support.

Selling, general and administrative

The increase in Selling, general and administrative (SG&A) expense for 2018 was driven primarily by investments in product launches and marketed product support.

The decrease in SG&A expense for 2017 was driven primarily by the expiration of the ENBREL residual royalty payments on October 31, 2016, offset partially by investments in product launches and marketed product support.

The ENBREL co-promotion term expired in October 2013, and we were required to pay Pfizer residual royalties on a declining percentage of ENBREL net sales in the United States and Canada. Effective November 2016, there were no further residual royalty payments. The residual royalty percentage ranged from 10% to 11% in 2016.

Other

Other operating expenses for 2018 included a $330 million impairment charge associated with an intangible asset acquired in a business combination and a $42 million favorable net change in the fair values of contingent consideration. See Part IV—Note 14, Goodwill and other intangible assets, to the Consolidated Financial Statements.

Other operating expenses for 2017 included $284 million of impairment-related charges associated with an intangible asset acquired in a business combination and $83 million of certain net charges related to our restructuring plan.

Other operating expenses for 2016 included $105 million of charges related to legal proceedings.

Nonoperating expenses/income and income taxes

Nonoperating expenses/income and income taxes were as follows (dollar amounts in millions):

	Years ended December 31,		
	2018	2017	2016
Interest expense, net	$ 1,392	$ 1,304	$ 1,260
Interest and other income, net	$ 674	$ 928	$ 629
Provision for income taxes	$ 1,151	$ 7,618	$ 1,441
Effective tax rate	12.1 %	79.4 %	15.7 %

Interest expense, net

The increase in Interest expense, net, for 2018 was due primarily to the impact of rising interest rates on variable-rate debt.

The increase in Interest expense, net, for 2017 was due primarily to a higher average amount of debt outstanding compared with the prior year.

Interest and other income, net

The decrease in Interest and other income, net, for 2018 was due primarily to higher investment losses and lower interest income as a result of the liquidation of a portion of our portfolio, offset partially by gains on our equity investments and a net gain recognized in connection with our acquisition of K-A in the first quarter of 2018. See Part IV—Note 3, Business combinations, to the Consolidated Financial Statements.

The increase in Interest and other income, net, for 2017 was due primarily to higher interest income that resulted from higher average investment balances and higher gains on strategic investments.

Income taxes

The decrease in our effective tax rate for 2018 compared with 2017 was due primarily to impacts of U.S. corporate tax reform.

On December 22, 2017, the United States enacted the 2017 Tax Act, which imposes a repatriation tax on accumulated earnings of foreign subsidiaries, imposes a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (SAB 118), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We have completed our accounting for the tax effects of the 2017 Tax Act, including the repatriation tax, the net deferred tax remeasurement and the impact on our unrealized tax benefits. None of the adjustments we made to our provisional amounts were material to our consolidated financial statements.

As previously disclosed, we received a RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Final resolution of this complex matter is not likely within the next 12 months and could have a material impact on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued.

See Summary of Critical Accounting Policies—Income taxes, and Part IV—Note 7, Income taxes, to the Consolidated Financial Statements.

Financial Condition, Liquidity and Capital Resources

Selected financial data was as follows (in millions):

	December 31,	
	2018	2017
Cash, cash equivalents and marketable securities	$ 29,304	$ 41,678
Total assets	$ 66,416	$ 79,954
Current portion of long-term debt	$ 4,419	$ 1,152
Long-term debt	$ 29,510	$ 34,190
Stockholders' equity	$ 12,500	$ 25,241

Cash, cash equivalents and marketable securities

We have global access to our $29.3 billion balance of cash, cash equivalents and marketable securities, as we no longer reinvest the related undistributed foreign earnings indefinitely outside the United States. As a result of the 2017 Tax Act, we recorded a repatriation tax liability on undistributed earnings generated from operations in foreign tax jurisdictions estimated at $7.3 billion, which will be paid over eight years. The first annual payment was made in April 2018. See Contractual Obligations below.

The primary objective of our investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings and places restrictions on maturities and concentration by asset class and issuer.

Capital allocation

Consistent with the objective to optimize our capital structure, we seek to deploy our accumulated cash balances in an efficient manner, and we consider several alternatives such as payment of dividends, stock repurchases, repayment of debt, and strategic transactions that expand our portfolio of products in areas of therapeutic interest.

We intend to continue to invest in our business and return capital to stockholders through the payment of cash dividends and stock repurchases reflecting our confidence in the future cash flows of our business. The timing and amount of future dividends and stock repurchases will vary based on a number of factors, including future capital requirements for strategic transactions, the availability of financing on acceptable terms, debt service requirements, our credit rating, changes to applicable tax laws or corporate laws, changes to our business model and periodic determination by our Board of Directors that cash dividends and/or stock repurchases are in the best interests of stockholders and are in compliance with applicable laws and agreements of the Company. In addition, the timing and amount of stock repurchases may also be affected by the stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include private block purchases, tender offers and market transactions.

The Board of Directors declared quarterly cash dividends of $1.00 per share of common stock paid in 2016, increased our quarterly cash dividend by 15% to $1.15 per share of common stock paid in 2017, and increased our quarterly cash dividend by 15% to $1.32 per share of common stock paid in 2018. In December 2018, the Board of Directors declared a cash dividend of $1.45 per share of common stock for the first quarter of 2019, an increase of 10% for this period, to be paid in March 2019.

We have also returned capital to stockholders through our stock repurchase program. During 2018, we repurchased $17.9 billion of common stock and had cash settlements of $17.8 billion, which included 52.1 million shares of common stock repurchased through a $10.0 billion tender offer. In 2017 and 2016, we repurchased $3.1 billion and $3.0 billion of our common stock, respectively. As of December 31, 2018, $5.1 billion remained available under the stock repurchase program.

As a result of stock repurchases, including our recent tender offer, and quarterly dividend payments, we have an accumulated deficit as of December 31, 2018 and 2017. Our accumulated deficit is not expected to affect our future

ability to operate, repurchase stock, pay dividends or repay our debt given our continuing profitability and strong financial position.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt

markets and equity markets. See Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business*.

Financing arrangements

The current and noncurrent portions of our long-term borrowings as of December 31, 2018, were $4.4 billion and $29.5 billion, respectively. The current and noncurrent portions of our long-term borrowings as of December 31, 2017, were $1.2 billion and $34.2 billion, respectively. As of December 31, 2018, Standard & Poor's Financial Services LLC (S&P), Moody's Investors Service, Inc. (Moody's) and Fitch Ratings Inc. (Fitch) assigned credit ratings to our outstanding senior notes of A with a stable outlook, Baa1 with a stable outlook and BBB with a stable outlook, respectively, which are considered investment grade. Unfavorable changes to these ratings may have an adverse impact on future financings.

During 2018, we did not issue any debt or debt securities. During 2017 and 2016, we issued debt with aggregate principal amounts of $4.5 billion and $7.3 billion, respectively. During 2018, 2017 and 2016, we repaid debt of $1.1 billion, $4.4 billion and $3.7 billion, respectively.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating London Interbank Offered Rates (LIBOR)-based coupon over the life of the respective note. These interest rate swap contracts qualify and are designated as fair value hedges. As of December 31, 2018 and 2017, we had interest rate swap contracts with aggregate notional amounts of $10.95 billion and $9.45 billion, respectively.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts, which effectively convert the interest payments and principal repayment of the respective notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts qualify and are designated as cash flow hedges. As of December 31, 2018 and 2017, we had cross-currency swap contracts with aggregate notional amounts of $5.6 billion.

As of December 31, 2018, we had a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. During 2017, we issued and repaid an aggregate of $12.3 billion commercial paper and had a maximum outstanding balance of $1.5 billion under our commercial paper program. During 2018 and 2016, we did not issue any commercial paper. No commercial paper was outstanding as of December 31, 2018 or 2017.

In 2014, we entered into a $2.5 billion syndicated, unsecured, revolving credit agreement which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $500 million with the agreement of the banks. Each bank which is a party to the agreement has an initial commitment term of five years. We extended this term by one year during 2016 and may extend the term for an additional year with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest at LIBOR plus 1% for any amounts borrowed under this facility. As of December 31, 2018 and 2017, no amounts were outstanding under this facility.

In 2017, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2020.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which was modified during 2018. The modified covenant requires that we maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest expense, each as defined and described in the amended credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2018.

See Part IV—Note 16, Financing arrangements, and Note 19, Derivative instruments, to the Consolidated Financial Statements.

Cash flows

Our summarized cash flow activity was as follows (in millions):

	Years ended December 31,		
	2018	2017	2016
Net cash provided by operating activities	$ 11,296	$ 11,177	$ 10,354
Net cash provided by (used in) investing activities	$ 14,339	$ (4,024)	$ (8,658)
Net cash used in financing activities	$ (22,490)	$ (6,594)	$ (2,599)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities increased during 2018 due primarily to improvements in working capital, offset partially by higher payments to taxing authorities. Cash provided by operating activities increased during 2017 due primarily to higher operating margin and the timing of payments to vendors and receipts from customers, offset partially by higher payments to taxing authorities.

Investing

Cash provided by investing activities during 2018 was due primarily to net cash inflows related to marketable securities of $15.0 billion and cash used in investing activities during 2017 and 2016 was due primarily to net cash outflows related to marketable securities of $3.2 billion, and $7.7 billion, respectively. Capital expenditures, which were associated primarily with site development costs, including our Thousand Oaks campus, as well as the new next-generation biomanufacturing facility in Rhode Island and life-cycle investments across the manufacturing network, were $738 million, $664 million and $738 million in 2018, 2017 and 2016, respectively. We currently estimate 2019 spending on capital projects to be approximately $700 million.

Financing

Cash used in financing activities during 2018 was due primarily to repurchases of our common stock of $17.8 billion, the payment of dividends of $3.5 billion, repayment of debt of $1.1 billion and withholding taxes arising from shares withheld for share-based payments of $126 million. Cash used in financing activities during 2017 was due primarily to the payment of dividends of $3.4 billion, repurchases of our common stock of $3.2 billion and withholding taxes arising from shares withheld for share-based payments of $191 million, offset partially by proceeds from the issuance of debt, net of repayment, of $71 million. Cash used in financing activities during 2016 was due primarily to the payment of dividends of $3.0 billion, repurchases of our common stock of $3.0 billion and withholding taxes arising from shares withheld for share-based payments of $260 million, offset partially by proceeds from the issuance of debt, net of repayment, of $3.6 billion.

See Part IV—Note 16, Financing arrangements, and Note 17, Stockholders' equity, to the Consolidated Financial Statements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are material or reasonably likely to become material to our consolidated financial position or consolidated results of operations.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payment. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information. Timing of payments and actual amounts paid may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations.

The following table represents our contractual obligations aggregated by type (in millions):

	Payments due by period as of December 31, 2018				
Contractual obligations	**Total**	**Year 1**	**Years 2 and 3**	**Years 4 and 5**	**Years 6 and beyond**
Long-term debt obligations [1] [2] [3]	$ 54,276	$ 5,856	$ 8,777	$ 7,444	$ 32,199
Operating lease obligations [4]	569	164	239	120	46
Purchase obligations [5]	1,153	609	305	124	115
U.S. repatriation tax [6]	6,739	586	1,172	1,685	3,296
Unrecognized tax benefits (UTBs) [7]	—	—	—	—	—
Total contractual obligations	$ 62,737	$ 7,215	$ 10,493	$ 9,373	$ 35,656

(1) Long-term debt obligations include future interest payments on our fixed-rate obligations at the contractual coupon rates. To achieve a desired mix of fixed-rate and floating-rate debt, we enter into interest rate swap contracts that effectively convert a fixed-rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the terms of the related hedge contracts. We used an interest rate forward curve as of December 31, 2018, in computing net amounts to be paid or received under our interest rate swap contracts, which resulted in an aggregate net increase in future interest payments of $77 million. See Part IV —Note 16, Financing arrangements, to the Consolidated Financial Statements.

(2) Long-term debt obligations include future interest payments on our LIBOR-based variable-rate obligations. We used an interest rate forward curve as of December 31, 2018, in computing the LIBOR-based portion of interest payments on these debt obligations. See Part IV—Note 16, Financing arrangements, to the Consolidated Financial Statements.

(3) Long-term debt obligations include contractual interest payments and principal repayment of our foreign-denominated debt obligations. In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our euro-, pound-sterling- and Swiss-franc-denominated long-term debt, we enter into cross-currency swap contracts that effectively convert interest payments and principal repayment on this debt from euros, pounds sterling and Swiss francs to U.S. dollars. For purposes of this table, we used the contracted exchange rates in the cross-currency swap contracts to compute the net amounts of future interest payments and principal repayments on this debt. See Part IV—Note 19, Derivative instruments, to the Consolidated Financial Statements.

(4) Operating lease obligations exclude $203 million of future receipts under noncancelable subleases of abandoned facilities.

(5) Purchase obligations relate primarily to: (i) R&D commitments (including those related to clinical trials) for new and existing products; (ii) capital expenditures; and (iii) open purchase orders for the acquisition of goods and services in the ordinary course of business. Our obligation to pay certain of these amounts may be reduced based on certain future events.

(6) Under the 2017 Tax Act, we elected to pay the repatriation tax related primarily to our prior indefinitely invested earnings of our foreign operations in eight annual installments. See Part IV—Note 7, Income taxes, to the Consolidated Financial Statements.

(7) Liabilities for UTBs (net of foreign tax credits and federal tax benefit of state taxes) and related accrued interest and penalties of $2.6 billion as of December 31, 2018, are not included in the table above because, due to their nature, there is a high degree of uncertainty regarding the timing of future cash outflows and other events that extinguish these liabilities.

In addition to amounts in the table above, we are contractually obligated to pay additional amounts, which in the aggregate are significant, upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties, including contingent consideration incurred in the acquisition of K-A and BioVex Group Inc. (BioVex). These payments are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring. These contingent payments have not

been included in the table above, and, except with respect to the fair value of the contingent consideration obligations, are not recorded on our Consolidated Balance Sheets. As of December 31, 2018, the maximum amount that may be payable in the future for agreements we have entered into with third parties is $7.5 billion, including $325 million of contingent consideration payments in connection with the acquisition of BioVex. Contingent consideration with respect to the acquisition of Dezima Pharma B.V. was excluded due to the discontinuation of the development of AMG 899, upon which payments are based. See Part IV—Note 18, Fair value measurement, to the Consolidated Financial Statements.

Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate. Accruals are also adjusted to reflect actual results. Amounts recorded in Accrued liabilities in the Consolidated Balance Sheets for sales deductions were as follows (in millions):

	Rebates	Chargebacks	Other deductions	Total
Balance as of December 31, 2015	$ 1,119	$ 273	$ 94	$ 1,486
Amounts charged against product sales	3,479	5,270	905	9,654
Payments	(3,181)	(5,201)	(884)	(9,266)
Balance as of December 31, 2016	1,417	342	115	1,874
Amounts charged against product sales	4,909	6,098	992	11,999
Payments	(4,459)	(6,168)	(999)	(11,626)
Balance as of December 31, 2017	1,867	272	108	2,247
Amounts charged against product sales	6,180	6,926	1,180	14,286
Payments	(5,458)	(6,744)	(1,161)	(13,363)
Balance as of December 31, 2018	$ 2,589	$ 454	$ 127	$ 3,170

For the years ended December 31, 2018, 2017 and 2016, total sales deductions were 39%, 35% and 31% of gross product sales, respectively. The increase in the total sales deductions balance as of December 31, 2018 compared to December 31, 2017, was driven primarily by the impact of higher sales, increases in U.S. rebates and chargebacks, as well as timing of payments. Included in the amounts are immaterial net adjustments related to prior-year sales due to changes in estimates. Such amounts represent less than 1% of the aggregate sales deductions charged against product sales in the years ended December 31, 2016, 2017 and 2018.

In the United States, we utilize wholesalers as the principal means of distributing our products to healthcare providers, such as physicians or their clinics, dialysis centers, hospitals and pharmacies. Products we sell in Europe are distributed principally to hospitals and/or wholesalers depending on the distribution practice in each country where the products are sold. We monitor the inventory levels of our products at our wholesalers by using data from our wholesalers and other third parties, and we believe wholesaler inventories have been maintained at appropriate levels (generally two to three weeks) given end-user demand. Accordingly, historical fluctuations in wholesaler inventory levels have not significantly affected our method of estimating sales deductions and returns.

Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given year, can be affected by the mix of products sold.

Rebates include primarily amounts paid to payers and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements, which vary by product, by payer and by individual payer plans. As we sell products, we estimate the amount of rebate we will pay based on the product sold, contractual terms, estimated patient population, historical experience and wholesaler inventory levels, and we accrue these rebates in the period the related sales are recorded. We then adjust the rebate accruals as more information becomes available and to reflect actual claims experience. Estimating such rebates is complicated, in part because of the time delay between the date of sale and the actual settlement of the liability. We

believe the methodology we use to accrue for rebates is reasonable and appropriate given current facts and circumstances, but actual results may differ.

Wholesaler chargebacks relate to our contractual agreements to sell products to healthcare providers in the United States at fixed prices that are lower than the prices we charge wholesalers. When healthcare providers purchase our products through wholesalers at these reduced prices, wholesalers charge us for the difference between their purchase prices and the contractual prices between Amgen and the healthcare providers. The provision for chargebacks is based on the expected sales by our wholesaler customers to healthcare providers. Accruals for wholesaler chargebacks are less difficult to estimate than rebates are, and they closely approximate actual results since chargeback amounts are fixed at the date of purchase by the healthcare providers and because we generally settle the liability for these deductions within a few weeks.

Product returns

Returns are estimated through comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. In each of the past three years, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-year sales return provisions have historically been immaterial.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is measured based on the largest benefit that is more likely than not to be realized. The amount of UTBs is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We believe our estimates for uncertain tax positions are appropriate and sufficient for any assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense.

Certain items are included in our tax return at different times than they are reflected in the financial statements and cause temporary differences between the tax bases of assets and liabilities and their reported amounts. Such temporary differences create deferred tax assets and liabilities. Deferred tax assets are generally items that can be used as a tax deduction or credit in the tax return in future years but for which we have already recorded the tax benefit in the consolidated financial statements. We establish valuation allowances against our deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities are either: (i) tax expenses recognized in the consolidated financial statements for which payment has been deferred; (ii) expenses for which we have already taken a deduction on the tax return, but have not yet recognized the expense in the consolidated financial statements; or (iii) liabilities for the difference between the book basis and tax basis of the intangible assets acquired in many business combinations, as future expenses associated with these assets most often will not be tax deductible.

We are a vertically integrated enterprise with operations in the United States and various foreign jurisdictions. We are subject to income tax in the foreign jurisdictions where we conduct activities based on the tax laws and principles of such jurisdictions and the functions, risks and activities performed therein. Our pretax income is therefore attributed to domestic or foreign sources based on the operations performed and risks assumed in each location and the tax laws and principles of the respective taxing jurisdictions. For example, we conduct significant operations in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes, pertaining to manufacturing, distribution and other related functions to meet our worldwide product demand. Income from our operations in Puerto Rico is subject to tax incentive grants through 2035.

On December 22, 2017, the United States enacted the 2017 Tax Act, which imposes a repatriation tax on accumulated earnings of foreign subsidiaries, imposes a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. In December 2017, the SEC staff issued SAB 118, which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We have completed our accounting for the tax effects of the 2017 Tax Act, including the repatriation tax, the net deferred tax remeasurement and the impact on our unrealized tax benefits. None of the adjustments we made to our provisional amounts were material to our consolidated financial statements.

As previously disclosed, we received a RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Final resolution of this complex matter is not likely within the next 12 months and could have a material impact on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the

complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. See Part IV—Note 7, Income taxes, to the Consolidated Financial Statements.

Our operations are subject to the tax laws, regulations and administrative practices of the United States, U.S. state jurisdictions and other countries, including the U.S. territory of Puerto Rico, in which we do business. Significant changes in these rules could have a material adverse effect on our results of operations. See Part I, Item 1A. Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability*.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters such as intellectual property disputes, contractual disputes and class action suits which are complex in nature and have outcomes that are difficult to predict. We describe our legal proceedings and other matters that are significant or that we believe could become significant in Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Valuation of assets and liabilities in connection with business combinations

We have acquired and continue to acquire intangible assets in connection with business combinations. These intangible assets consist primarily of technology associated with currently marketed human therapeutic products and IPR&D product candidates. Discounted cash flow models are typically used to determine the fair values of these intangible assets for purposes of allocating consideration paid to the net assets acquired in a business combination. See Part IV—Note 3, Business combinations, to the Consolidated Financial Statements. These models require the use of significant estimates and assumptions, including, but not limited to:

- determining the timing and expected costs to complete in-process projects, taking into account the stage of completion at the acquisition date;
- projecting the probability and timing of obtaining marketing approval from the FDA and other regulatory agencies for product candidates;
- estimating the timing of and future net cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates to calculate the present values of the cash flows.

Significant estimates and assumptions are also required to determine the acquisition date fair values of any contingent consideration obligations incurred in connection with business combinations. In addition, we must revalue these obligations each subsequent reporting period until the related contingencies are resolved and record changes in their fair values in earnings. The acquisition date fair values of contingent consideration obligations incurred or assumed in the acquisitions of businesses were determined using a combination of valuation techniques. Significant estimates and assumptions required for these valuations included, but were not limited to, the probability of achieving regulatory milestones, product sales projections under various scenarios and discount rates used to calculate the present value of the required payments. These estimates and assumptions are required to be updated in order to revalue these contingent consideration obligations each reporting period. Accordingly, subsequent changes in underlying facts and circumstances could result in changes in these estimates and assumptions, which could have a material impact on the estimated future fair values of these obligations.

We believe the fair values used to record intangible assets acquired and contingent consideration obligations incurred in connection with business combinations are based on reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Impairment of long-lived assets

We review the carrying value of our property, plant and equipment and our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows to be generated by the long-lived asset is compared to the

carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value.

Indefinite-lived intangible assets, composed of IPR&D projects acquired in a business combination that have not reached technological feasibility or that lack regulatory approval at the time of acquisition, are reviewed for impairment annually, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon establishment of technological feasibility or regulatory approval. We determine impairment by comparing the fair value of the asset to its carrying value. If the asset's carrying value exceeds its fair value, an impairment charge is recorded for the difference and its carrying value is reduced accordingly.

Estimating future cash flows of an IPR&D product candidate for purposes of an impairment analysis requires us to make significant estimates and assumptions regarding the amount and timing of costs to complete the project and the amount, timing and probability of achieving revenues from the completed product similar to how the acquisition date fair value of the project was determined, as described above. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market these products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods which could have a material adverse effect on our results of operations.

We believe our estimations of future cash flows used for assessing impairment of long-lived assets are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

Recently Issued Accounting Standards

See Part IV—Note 1, Summary of significant accounting policies, to the Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 31, 2018.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks that may result from changes in interest rates, foreign currency exchange rates and prices of equity instruments as well as changes in general economic conditions in the countries where we conduct business. To reduce certain of these risks, we enter into various types of foreign currency and interest rate derivative hedging transactions as part of our risk management program. We do not use derivatives for speculative trading purposes.

In the discussion that follows, we have assumed a hypothetical change in interest rates of 100 basis points from those as of December 31, 2018 and 2017. We have also assumed a hypothetical 20% change in foreign currency exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2018 and 2017.

Interest-rate-sensitive financial instruments

Our portfolio of available-for-sale interest-bearing securities as of December 31, 2018 and 2017, was composed of U.S. Treasury securities and other government-related debt securities, corporate debt securities, residential mortgage-backed and other mortgage- and asset-backed securities, money market mutual funds and other short-term interest-bearing securities composed principally of commercial paper. The fair values of our investment portfolio of interest-bearing securities were $28.7 billion and $41.2 billion as of December 31, 2018 and 2017, respectively. Duration is a sensitivity measure that can be used to approximate the change in the value of a security that will result from a 100 basis point change in interest rates. Applying a duration model, a hypothetical 100 basis point increase in interest rates as of December 31, 2018 and 2017, would have resulted in reductions in the fair values of these securities of $360 million and $1.1 billion, respectively, on these dates. In addition, a hypothetical 100 basis point decrease in interest rates as of December 31, 2018 and 2017, would not result in a material effect on income in the respective ensuing year.

As of December 31, 2018, we had outstanding debt with a carrying value of $33.9 billion and a fair value of $35.0 billion. As of December 31, 2017, we had outstanding debt with a carrying value of $35.3 billion and a fair value of $38.6 billion. Our outstanding debt was composed primarily of debt with fixed interest rates, with variable-rate debt having carrying values of $850 million as of December 31, 2018 and 2017. Changes in interest rates do not affect interest expense on fixed-rate debt. Changes in interest rates would, however, affect the fair values of fixed-

rate debt. A hypothetical 100 basis point decrease in interest rates relative to interest rates as of December 31, 2018 and 2017, would have resulted in increases of $2.6 billion and $3.3 billion, respectively, in the aggregate fair value of our outstanding debt on each of these dates. Analysis of the debt does not consider the impact that hypothetical changes in interest rates would have on the related interest rate swap contracts and cross-currency swap contracts, discussed below.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified and were designated for accounting purposes as fair value hedges for certain of our fixed-rate debt. These interest rate swap contracts effectively converted a fixed-rate interest coupon to a floating-rate LIBOR-based coupon over the life of the respective note. Interest rate swap contracts with aggregate notional amounts of $10.95 billion and $9.45 billion were outstanding as of December 31, 2018 and 2017, respectively. A hypothetical 100 basis point increase in interest rates relative to interest rates as of December 31, 2018 and 2017, would have resulted in reductions in fair values of $460 million and $420 million, respectively, on our interest rate swap contracts on these dates and would not result in a material effect on the related income in the respective ensuing years. Analysis of the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair values of debt that these interest-rate-sensitive instruments were designed to offset.

As of December 31, 2018 and 2017, we had outstanding cross-currency swap contracts with aggregate notional amounts of $5.6 billion that hedge certain of our foreign-currency-denominated debt and related interest payments. These contracts effectively convert interest payments and principal repayment of this debt to U.S. dollars from euros, pounds sterling and Swiss francs and are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates as of December 31, 2018 and 2017, would have resulted in reductions in the fair values of our cross-currency swap contracts of $320 million and $390 million, respectively.

Foreign-currency-sensitive financial instruments

Our international operations are affected by fluctuations in the value of the U.S. dollar as compared to foreign currencies, predominantly the euro. Increases and decreases in our international product sales from movements in foreign currency exchange rates are offset partially by the corresponding increases or decreases in our international operating expenses. Increases and decreases in our foreign-currency-denominated assets from movements in foreign currency exchange rates are offset partially by the corresponding increases or decreases in our foreign-currency-denominated liabilities. To further reduce our net exposure to foreign currency exchange rate fluctuations on our results of operations, we enter into foreign currency forward, option and cross-currency swap contracts.

As of December 31, 2018, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and fair value of $5.3 billion and $5.6 billion, respectively. As of December 31, 2017, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and fair value of $6.2 billion and $6.7 billion, respectively. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2018, would have resulted in an increase in fair value of this debt of $1.1 billion on this date and a reduction in income in the ensuing year of $1.1 billion. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2017, would have resulted in an increase in fair value of this debt of $1.3 billion on this date and a reduction in income in the ensuing year of $1.2 billion. The impact on income from these hypothetical changes in foreign currency exchange rates would be substantially offset by the impact such changes would have on related cross-currency swap contracts, which are in place for the related foreign-currency-denominated debt.

We have cross-currency swap contracts that are designated as cash flow hedges of certain of our debt denominated in euros, pounds sterling and Swiss francs with an aggregate notional amount of $5.6 billion, as of December 31, 2018 and 2017. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would have resulted in reductions in the fair values of these contracts of $1.2 billion and $1.3 billion on these dates, respectively. The impact of this hypothetical adverse movement in foreign currency exchange rates on ensuing years' income from these contracts would be fully offset by the corresponding hypothetical changes in the carrying amounts of the related hedged debt.

We enter into foreign currency forward and options contracts that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2018, we had open foreign currency forward and option contracts, primarily euro based with notional amounts of $4.5 billion and $21 million, respectively. As of December 31, 2017, we had open foreign currency forward and option contracts, primarily euro based with notional amounts of $4.6 billion and $74 million, respectively. As of December 31, 2018 the fair values of these contracts were a $181 million asset and a $26 million liability. As of December 31, 2017 the fair values of these contracts were a $6 million asset and a $204 million liability. With regard to foreign currency forward and option contracts that were open as of December 31, 2018, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2018, would have resulted in a reduction in fair value of these contracts of $810 million on this date and, in the ensuing year, a reduction in income of $380 million. With regard to contracts that were open as of December 31, 2017, a

hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2017, would have resulted in a reduction in fair value of these contracts of $930 million on this date and, in the ensuing year, a reduction in income of $360 million. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign-currency-sensitive instruments were designed to offset.

As of December 31, 2018 and 2017, we had open foreign currency forward contracts with notional amounts of $737 million and $757 million, respectively, that hedged fluctuations of certain assets and liabilities denominated in foreign currencies but were not designated as hedges for accounting purposes. These contracts had no material net unrealized gains or losses as of December 31, 2018 and 2017. With regard to these foreign currency forward contracts that were open as of December 31, 2018 and 2017, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would not have a material effect on the fair values of these contracts or related income in the respective ensuing years. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on assets and liabilities that these foreign-currency-sensitive instruments were designed to offset.

Market-price-sensitive financial instruments

As of December 31, 2018 and 2017, we were also exposed to price risk on equity securities included in our portfolio of investments, which were acquired primarily for the promotion of business and strategic objectives. These investments are generally in small-capitalization stocks in the biotechnology industry sector. Price risk relative to our equity investment portfolio as of December 31, 2018 and 2017, was not material.

Counterparty credit risks

Our financial instruments, including derivatives, are subject to counterparty credit risk, which we consider as part of the overall fair value measurement. Our financial risk management policy limits derivative transactions by requiring transactions to be with institutions with minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch and requires placing exposure limits on the amount with any individual counterparty. In addition, we have an investment policy that limits investments to certain types of debt and money market instruments issued by institutions primarily with investment-grade credit ratings and places restriction on maturities and concentrations by asset class and issuer.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is incorporated herein by reference to the financial statements and schedule listed in Item 15(a)1 and (a)2 of Part IV and included in this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under the Securities Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance Amgen's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2018.

Management determined that, as of December 31, 2018, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States. However, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and reporting.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our assessment, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

The effectiveness of the Company's internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing below, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2018.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Amgen Inc.

Opinion on Internal Control over Financial Reporting

We have audited Amgen Inc.'s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Amgen Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Amgen Inc. as of December 31, 2018 and 2017, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 and our report dated February 13, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Los Angeles, California
February 13, 2019

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about our Directors is incorporated by reference from the section entitled ITEM 1—ELECTION OF DIRECTORS in our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2018 (the Proxy Statement). Information about compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated by reference from the section entitled OTHER MATTERS—Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement. Information about the procedures by which stockholders may recommend nominees for the Board of Directors is incorporated by reference from APPENDIX A—AMGEN INC. BOARD OF DIRECTORS GUIDELINES FOR DIRECTOR QUALIFICATIONS AND EVALUATIONS and OTHER MATTERS—Stockholder Proposals for the 2020 Annual Meeting in our Proxy Statement. Information about our Audit Committee, members of the committee and our Audit Committee financial experts is incorporated by reference from the section entitled CORPORATE GOVERNANCE—Audit Committee in our Proxy Statement. Information about our executive officers is contained in the discussion entitled Part I—Item 1. Business—Executive Officers of the Registrant.

Code of Ethics

We maintain a Code of Ethics for the Chief Executive Officer and Senior Financial Officers applicable to our principal executive officer, principal financial officer, principal accounting officer or controller, and other persons performing similar functions. To view this code of ethics free of charge, please visit our website at www.amgen.com. (This website address is not intended to function as a hyperlink, and the information contained in our website is not intended to be a part of this filing.) We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics, if any, by posting such information on our website as set forth above.

Item 11. EXECUTIVE COMPENSATION

Information about director and executive compensation is incorporated by reference from the section entitled EXECUTIVE COMPENSATION in our Proxy Statement. Information about compensation committee matters is incorporated by reference from the sections entitled CORPORATE GOVERNANCE—Compensation and Management Development Committee and CORPORATE GOVERNANCE—Compensation Committee Report in our Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table sets forth certain information as of December 31, 2018, concerning the shares of our common stock that may be issued under any form of award granted under our equity compensation plans in effect as of December 31, 2018 (including upon the exercise of options, the vesting of awards of restricted stock units (RSUs), or when performance units are earned, and related dividend equivalents have been granted).

Plan category	(a) Number of securities to be issued upon exercise of outstanding options and rights	(b) Weighted-average exercise price of outstanding options and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by Amgen security holders:			
Amended and Restated 2009 Equity Incentive Plan[1]	9,900,975	$ 143.61	32,159,877
Amended and Restated 1991 Equity Incentive Plan[2]	17,030	—	—
Amended and Restated Employee Stock Purchase Plan	—	—	4,634,563
Total approved plans	9,918,005	143.61	36,794,440
Equity compensation plan not approved by Amgen security holders:			
Amgen Profit Sharing Plan for Employees in Ireland[3]	—	—	95,087
Total unapproved plans	—	—	95,087
Total all plans	9,918,005	$ 143.61	36,889,527

(1) The Amended and Restated 2009 Equity Incentive Plan employs a fungible share counting formula for determining the number of shares available for issuance under the plan. In accordance with this formula, each option or stock appreciation right counts as one share, while each restricted stock unit, performance unit or dividend equivalent counts as 1.9 shares. The number under column (a) represents the actual number of shares issuable under our outstanding awards without giving effect to the fungible share counting formula. The number under column (c) represents the number of shares available for issuance under this plan based on each such available share counting as one share. Commencing with the grants made in April 2012, RSUs and performance units accrue dividend equivalents that are payable in shares only to the extent and when the underlying RSUs vest or underlying performance units have been earned and the related shares are issued to the grantee. The performance units granted under this plan are earned based on the accomplishment of specified performance goals at the end of their respective three-year performance periods; the number of performance units granted represent target performance and the maximum number of units that could be earned based on our performance is 200% of the performance units granted in 2016, 2017 and 2018.

As of December 31, 2018, the number of outstanding awards under column (a) includes: (i) 4,412,073 shares issuable upon the exercise of outstanding options with a weighted-average exercise price of $143.61; (ii) 3,365,817 shares issuable upon the vesting of outstanding RSUs (including 172,613 related dividend equivalents); and (iii) 2,123,085 shares subject to outstanding 2016, 2017 and 2018 performance units (including 94,881 related dividend equivalents). The weighted-average exercise price shown in column (b) is for the outstanding options only. The number of available shares under column (c) represents the number of shares that remain available for future issuance under this plan as of December 31, 2018, employing the fungible share formula and presumes the issuance of target shares under the performance units granted in 2016, 2017 and 2018 and related dividend equivalents. The numbers under columns (a) and (c) do not give effect to the additional shares that could be issuable in the event above target on the performance goals under these

outstanding performance units are achieved. Maximum performance under these goals could result in 200% of target shares being awarded for performance units granted in 2016, 2017 and 2018.

(2) This plan has terminated as to future grants. The number under column (a) with respect to this plan includes 17,030 shares issuable upon the settlement of deferred RSUs (including 2,577 related dividend equivalents).

(3) The Amgen Profit Sharing Plan for Employees in Ireland (the Profit Sharing Plan) was approved by the Board of Directors on July 28, 2011. The Profit Sharing Plan permits eligible employees of the Company's subsidiaries located in Ireland who participate in the Profit Sharing Plan to apply a portion of their qualifying bonus and salary to the purchase the Company's common stock on the open market at the market price by a third-party trustee as described in the Profit Sharing Plan.

Security Ownership of Directors and Executive Officers and Certain Beneficial Owners

Information about security ownership of certain beneficial owners and management is incorporated by reference from the sections entitled SECURITY OWNERSHIP OF DIRECTORS AND EXECUTIVE OFFICERS and SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS in our Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information about certain relationships and related transactions and director independence is incorporated by reference from the sections entitled CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS and CORPORATE GOVERNANCE—Director Independence in our Proxy Statement.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information about the fees for professional services rendered by our independent registered public accountants is incorporated by reference from the section entitled AUDIT MATTERS—Independent Registered Public Accountants in our Proxy Statement.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)1. Index to Financial Statements

The following Consolidated Financial Statements are included herein:

	Page number
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Statements of Income for each of the three years in the period ended December 31, 2018	F-2
Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2018	F-3
Consolidated Balance Sheets as of December 31, 2018 and 2017	F-4
Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2018	F-5
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2018	F-6
Notes to Consolidated Financial Statements	F-7

(a)2. Index to Financial Statement Schedules

The following Schedule is filed as part of this Annual Report on Form 10-K:

	Page number
II. Valuation and Qualifying Accounts	F-53

All other schedules are omitted because they are not applicable, not required or because the required information is included in the consolidated financial statements or notes thereto.

(a)3. Exhibits

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)

4.4 First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)

4.5 8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)

4.6 Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)

4.7 Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)

4.8 Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)

4.9 Officers' Certificate of Amgen Inc., dated May 30, 2007, including forms of the Company's Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)

4.10 Officers' Certificate of Amgen Inc., dated May 23, 2008, including forms of the Company's 6.15% Senior Notes due 2018 and 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)

4.11 Officers' Certificate of Amgen Inc., dated January 16, 2009, including forms of the Company's 5.70% Senior Notes due 2019 and 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)

4.12 Officers' Certificate of Amgen Inc., dated March 12, 2010, including forms of the Company's 4.50% Senior Notes due 2020 and 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.)

4.13 Officers' Certificate of Amgen Inc., dated September 16, 2010, including forms of the Company's 3.45% Senior Notes due 2020 and 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)

4.14 Officers' Certificate of Amgen Inc., dated June 30, 2011, including forms of the Company's 2.30% Senior Notes due 2016, 4.10% Senior Notes due 2021 and 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)

4.15 Officers' Certificate of Amgen Inc., dated November 10, 2011, including forms of the Company's 1.875% Senior Notes due 2014, 2.50% Senior Notes due 2016, 3.875% Senior Notes due 2021 and 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)

4.16 Officers' Certificate of Amgen Inc., dated December 5, 2011, including forms of the Company's 4.375% Senior Notes due 2018 and 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)

4.17 Officers' Certificate of Amgen Inc., dated May 15, 2012, including forms of the Company's 2.125% Senior Notes due 2017, 3.625% Senior Notes due 2022 and 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)

4.18 Officers' Certificate of Amgen Inc., dated September 13, 2012, including forms of the Company's 2.125% Senior Notes due 2019 and 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)

4.19 Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)

4.20 Officers' Certificate of Amgen Inc., dated May 22, 2014, including forms of the Company's Senior Floating Rate Notes due 2017, Senior Floating Rate Notes due 2019, 1.250% Senior Notes due 2017, 2.200% Senior Notes due 2019 and 3.625% Senior Notes due 2024. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)

4.21 Officer's Certificate of Amgen Inc., dated May 1, 2015, including forms of the Company's 2.125% Senior Notes due 2020, 2.700% Senior Notes due 2022, 3.125% Senior Notes due 2025 and 4.400% Senior Notes due 2045. (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.)

4.22 Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including forms of the Company's 1.250% Senior Notes due 2022 and 2.000% Senior Notes due 2026. (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.)

4.23 Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)

4.24 Terms of the Bonds for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)

4.25	Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.26	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 1.850% Senior Notes due 2021, 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of May 11, 2017 including forms of the Company's Senior Floating Rate Notes due 2019, Senior Floating Rate Notes due 2020, 1.900% Senior Notes due 2019, 2.200% Senior Notes due 2020 and 2.650% Senior Notes due 2022. (Filed as an exhibit to Form 8-K on May 11, 2017 and incorporated herein by reference.)
4.28	Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated by reference.)
10.1+	Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
10.2+	First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.)
10.3+	Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)
10.4+*	Form of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 7, 2018.)
10.5+*	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 7, 2018.)
10.6+	Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.7+*	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on December 7, 2018.)
10.8+	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on October 24, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.9+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.10+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on October 24, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.11+	Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.12+	Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.13+	

First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)

10.14+ Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.)

10.15+ Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)

10.16+ First Amendment to the Amgen Inc. Executive Incentive Plan, effective December 13, 2012. (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.)

10.17+ Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)

10.18+ Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)

10.19+ First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)

10.20+ Agreement between Amgen Inc. and David W. Meline, effective July 21, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2014 on October 29, 2014 and incorporated herein by reference.)

10.21+ Agreement between Amgen Inc. and Jonathan Graham, dated May 11, 2015. (Filed as an exhibit to Form 10-Q/A for the quarter ended June 30, 2015 on August 6, 2015 and incorporated herein by reference.)

10.22+ Agreement between Amgen Inc. and Lori Johnston, dated October 25, 2016. (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)

10.23+ Agreement between Amgen Inc. and Murdo Gordon, dated July 25, 2018. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2018 on October 31, 2018 and incorporated herein by reference.)

10.24 Amended and Restated Credit Agreement, dated July 30, 2014, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent (the "Credit Agreement"). (Filed as an exhibit to Form 8-K on July 30, 2014 and incorporated herein by reference.)

10.25 Amendment No. 1 to the Credit Agreement, dated March 9, 2018, among Amgen Inc., the Banks therein named, and Citibank, N.A., as administrative agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.)

10.26 Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)

10.27 Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)

10.28 Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)

10.29 Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)

10.30

Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)

10.31 Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)

10.32 Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)

10.33	Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
10.34	Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.35	Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.36	Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.37	Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.38	Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.39	Amendment No. 1 to the Collaboration Agreement, dated March 20, 2018, by and between Novartis Pharma AG and Amgen Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.)
21*	Subsidiaries of the Company
23	Consent of the Independent Registered Public Accounting Firm. The consent is set forth on page 74 of this Annual Report on the 10-K.
24	Power of Attorney. The Power of Attorney is set forth on page 75 of this Annual Report on Form 10-K.
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

(* = filed herewith)
(** = furnished herewith and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended)
(+ = management contract or compensatory plan or arrangement)

Item 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMGEN INC.
(Registrant)

Date: February 13, 2019

By: /s/ DAVID W. MELINE

David W. Meline
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-8 No. 333-159377) pertaining to the Amgen Inc. 2009 Equity Incentive Plan;

- Registration Statement (Form S-8 No. 33-39183) pertaining to the Amended and Restated Employee Stock Purchase Plan;

- Registration Statements (Form S-8 No. 33-39104, as amended by Form S-8 Nos. 333-144581 and 333-216719) pertaining to the Amended and Restated Amgen Retirement and Savings Plan (formerly known as the Amgen Retirement and Savings Plan);

- Registration Statements (Form S-8 Nos. 33-47605, 333-144580 and 333-216715) pertaining to the Retirement and Savings Plan for Amgen Manufacturing, Limited (formerly known as the Retirement and Savings Plan for Amgen Manufacturing, Inc.);

- Registration Statements (Form S-8 Nos. 333-81284, 333-177868 and 333-216723) pertaining to the Amgen Nonqualified Deferred Compensation Plan;

- Registration Statement (Form S-3 No. 333-216060) relating to debt securities, common stock, preferred stock, warrants to purchase debt securities, common stock, preferred stock or depositary shares, rights to purchase common stock or preferred stock, securities purchase contracts, securities purchase units and depositary shares of Amgen Inc. and in the related Prospectus; and

- Registration Statement (Form S-8 No. 333-176240) pertaining to the Amgen Profit Sharing Plan for Employees in Ireland;

of our reports dated February 13, 2019, with respect to the consolidated financial statements of Amgen Inc. and the effectiveness of internal control over financial reporting of Amgen Inc. included in this Annual Report (Form 10-K) of Amgen Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Los Angeles, California
February 13, 2019

EXHIBIT 24

POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David W. Meline, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming that said attorney-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/S/ ROBERT A. BRADWAY **Robert A. Bradway**	Chairman of the Board, Chief Executive Officer and President, and Director (Principal Executive Officer)	2/13/2019
/S/ DAVID W. MELINE **David W. Meline**	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	2/13/2019
/S/ WANDA M. AUSTIN **Wanda M. Austin**	Director	2/13/2019
/S/ BRIAN J. DRUKER **Brian J. Druker**	Director	2/13/2019
/S/ ROBERT A. ECKERT **Robert A. Eckert**	Director	2/13/2019
/S/ GREG C. GARLAND **Greg C. Garland**	Director	2/13/2019
/S/ FRED HASSAN **Fred Hassan**	Director	2/13/2019
/S/ REBECCA M. HENDERSON **Rebecca M. Henderson**	Director	2/13/2019
/S/ FRANK C. HERRINGER **Frank C. Herringer**	Director	2/13/2019
/S/ CHARLES M. HOLLEY, JR. **Charles M. Holley, Jr.**	Director	2/13/2019
/S/ TYLER JACKS **Tyler Jacks**	Director	2/13/2019
/S/ ELLEN J. KULLMAN **Ellen J. Kullman**	Director	2/13/2019
/S/ RONALD D. SUGAR **Ronald D. Sugar**	Director	2/13/2019
/S/ R. SANDERS WILLIAMS **R. Sanders Williams**	Director	2/13/2019

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Amgen Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amgen Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 13, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1980.

Los Angeles, California

February 13, 2019

AMGEN INC.

CONSOLIDATED STATEMENTS OF INCOME

Years ended December 31, 2018, 2017 and 2016

(In millions, except per-share data)

	2018	2017	2016
Revenues:			
Product sales	$ 22,533	$ 21,795	$ 21,892
Other revenues	1,214	1,054	1,099
Total revenues	23,747	22,849	22,991
Operating expenses:			
Cost of sales	4,101	4,069	4,162
Research and development	3,737	3,562	3,840
Selling, general and administrative	5,332	4,870	5,062
Other	314	375	133
Total operating expenses	13,484	12,876	13,197
Operating income	10,263	9,973	9,794
Interest expense, net	1,392	1,304	1,260
Interest and other income, net	674	928	629
Income before income taxes	9,545	9,597	9,163
Provision for income taxes	1,151	7,618	1,441
Net income	$ 8,394	$ 1,979	$ 7,722
Earnings per share:			
Basic	$ 12.70	$ 2.71	$ 10.32
Diluted	$ 12.62	$ 2.69	$ 10.24
Shares used in the calculation of earnings per share:			
Basic	661	731	748
Diluted	665	735	754

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Years ended December 31, 2018, 2017 and 2016

(In millions)

	2018	2017	2016
Net income	$ 8,394	$ 1,979	$ 7,722
Other comprehensive (loss) income, net of reclassification adjustments and taxes:			
(Losses) gains on foreign currency translation	(141)	81	(99)
Gains (losses) on cash flow hedges	247	(288)	(15)
(Losses) gains on available-for-sale securities	(185)	(6)	122
Other	(2)	5	1
Other comprehensive (loss) income, net of tax	(81)	(208)	9
Comprehensive income	$ 8,313	$ 1,771	$ 7,731

See accompanying notes.

AMGEN INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2018 and 2017

(In millions, except per-share data)

	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,945	$ 3,800
Marketable securities	22,359	37,878
Trade receivables, net	3,580	3,237
Inventories	2,940	2,834
Other current assets	1,794	1,727
Total current assets	37,618	49,476
Property, plant and equipment, net	4,958	4,989
Intangible assets, net	7,443	8,609
Goodwill	14,699	14,761
Other assets	1,698	2,119
Total assets	$ 66,416	$ 79,954
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,207	$ 1,352
Accrued liabilities	7,862	6,516
Current portion of long-term debt	4,419	1,152
Total current liabilities	13,488	9,020
Long-term debt	29,510	34,190
Long-term deferred tax liabilities	864	1,166
Long-term tax liabilities	8,770	9,099
Other noncurrent liabilities	1,284	1,238
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value per share; 2,750.0 shares authorized; outstanding—629.6 shares in 2018 and 722.2 shares in 2017	31,246	30,992
Accumulated deficit	(17,977)	(5,072)
Accumulated other comprehensive loss	(769)	(679)
Total stockholders' equity	12,500	25,241
Total liabilities and stockholders' equity	$ 66,416	$ 79,954

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended December 31, 2018, 2017 and 2016

(In millions)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of December 31, 2015	754.0	$ 30,649	$ (2,086)	$ (480)	$ 28,083
Net income	—	—	7,722	—	7,722
Other comprehensive income, net of tax	—	—	—	9	9
Dividends declared on common stock ($4.15 per share)	—	—	(3,120)	—	(3,120)
Issuance of common stock in connection with the Company's equity award programs	3.9	55	—	—	55
Stock-based compensation expense	—	342	—	—	342
Tax impact related to employee stock-based compensation expense	—	(262)	73	—	(189)
Repurchases of common stock	(19.7)	—	(3,027)	—	(3,027)
Balance as of December 31, 2016	738.2	30,784	(438)	(471)	29,875
Net income	—	—	1,979	—	1,979
Other comprehensive loss, net of tax	—	—	—	(208)	(208)
Dividends declared on common stock ($4.77 per share)	—	—	(3,487)	—	(3,487)
Issuance of common stock in connection with the Company's equity award programs	2.5	52	—	—	52
Stock-based compensation expense	—	347	—	—	347
Tax impact related to employee stock-based compensation expense	—	(191)	—	—	(191)
Repurchases of common stock	(18.5)	—	(3,126)	—	(3,126)
Balance as of December 31, 2017	722.2	30,992	(5,072)	(679)	25,241
Cumulative effect of changes in accounting principles, net of tax	—	—	38	(9)	29
Net income	—	—	8,394	—	8,394
Other comprehensive loss, net of tax	—	—	—	(81)	(81)
Dividends declared on common stock ($5.41 per share)	—	—	(3,482)	—	(3,482)
Issuance of common stock in connection with the Company's equity award programs	1.9	56	—	—	56
Stock-based compensation expense	—	327	—	—	327
Tax impact related to employee stock-based compensation expense	—	(129)	—	—	(129)
Repurchases of common stock	(94.5)	—	(17,855)	—	(17,855)
Balance as of December 31, 2018	629.6	$ 31,246	$ (17,977)	$ (769)	$ 12,500

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2018, 2017 and 2016

(In millions)

	2018	2017	2016
Cash flows from operating activities:			
Net income	$ 8,394	$ 1,979	$ 7,722
Depreciation and amortization	1,946	1,955	2,105
Stock-based compensation expense	311	329	311
Deferred income taxes	(363)	(1,330)	183
Other items, net	386	334	32
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	(378)	(58)	(214)
Inventories	(3)	133	(80)
Other assets	35	(24)	(128)
Accounts payable	(143)	424	(44)
Accrued income taxes, net	(361)	523	(301)
Long-term tax liabilities	258	6,681	445
Other liabilities	1,214	231	323
Net cash provided by operating activities	11,296	11,177	10,354
Cash flows from investing activities:			
Purchases of marketable securities	(18,741)	(33,607)	(28,094)
Proceeds from sales of marketable securities	28,356	24,240	17,958
Proceeds from maturities of marketable securities	5,412	6,174	2,459
Purchases of property, plant and equipment	(738)	(664)	(738)
Cash acquired in acquisition, net of cash paid	195	(19)	—
Other	(145)	(148)	(243)
Net cash provided by (used in) investing activities	14,339	(4,024)	(8,658)
Cash flows from financing activities:			
Net proceeds from issuance of debt	—	4,476	7,318
Repayment of debt	(1,121)	(4,405)	(3,725)
Repurchases of common stock	(17,794)	(3,160)	(2,965)
Dividends paid	(3,507)	(3,365)	(2,998)
Withholding taxes arising from shares withheld for share-based payments	(126)	(191)	(260)
Other	58	51	31
Net cash used in financing activities	(22,490)	(6,594)	(2,599)
Increase (decrease) in cash and cash equivalents	3,145	559	(903)
Cash and cash equivalents at beginning of year	3,800	3,241	4,144
Cash and cash equivalents at end of year	$ 6,945	$ 3,800	$ 3,241

See accompanying notes.

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2018

1. Summary of significant accounting policies

Business

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. We operate in one business segment: human therapeutics.

Principles of consolidation

The consolidated financial statements include the accounts of Amgen as well as its majority-owned subsidiaries. We do not have any significant interests in any variable interest entities. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Revenues

Adoption of new revenue recognition standard

In May 2014, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards require an entity to recognize revenue when control of promised goods or services is transferred to the customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted this new standard as of January 1, 2018, by applying the modified-retrospective method to those contracts that were not completed as of that date.

The results for reporting periods beginning after January 1, 2018, are presented in accordance with the new standard, although comparative information has not been restated and continues to be reported under the accounting standards and policies in effect for those periods.

Upon adoption, we recorded a net decrease of $25 million to Accumulated deficit due to the cumulative impact of adopting the new standard—with the impact related primarily to the acceleration of deferred revenue, net of related deferred tax impact. The adoption of this new standard had an immaterial impact on our reported total revenues and operating income as compared to what reported amounts would have been under the prior standard, and we expect the impact of adoption in future periods to also be immaterial. Our accounting policies under the new standard were applied prospectively and are described below. See Note 4, Revenues.

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that an adjustment is appropriate. Accruals are also adjusted to reflect actual results. Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given period, can be affected by the mix of products sold. Included in sales deductions are immaterial net adjustments related to prior-period sales due

to changes in estimates. Historically, such amounts have represented less than 1% of the aggregate sales deductions charged against product sales.

Returns are estimated through comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. Historically, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-period sales return provisions have historically been immaterial.

Our payment terms vary by types and locations of customers and the products or services offered. Payment terms differ by jurisdiction and customer, but payment is generally required in a term ranging from 30 to 120 days from date of shipment or satisfaction of the performance obligation. For certain products or services and certain customer types, we may require payment before products are delivered or services are rendered to customers.

Indirect taxes collected from customers and remitted to government authorities and that are related to sales of the Company's products, primarily in Europe, are excluded from revenues.

As a practical expedient, sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in Selling, general and administrative expense in the Consolidated Statements of Income.

Other revenues

Other revenues consist primarily of royalty income and corporate partner revenues. Royalties from licensees are based on third-party sales of licensed products and are recorded when the related third-party product sale occurs. Royalty estimates are based on historical and forecasted sales trends. Corporate partner revenues are composed mainly of license fees and milestones earned and our share of commercial profits generated from collaborations. See Arrangements with multiple-performance obligations, discussed below.

Arrangements with multiple-performance obligations

From time to time, we enter into arrangements for the research and development (R&D), manufacture and/or commercialization of products and product candidates. Such arrangements may require us to deliver various rights, services and/or goods, including intellectual property rights/licenses, R&D services, manufacturing services and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to Amgen in the form of nonrefundable upfront license fees, development and commercial performance milestone payments, royalty payments and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods or services is transferred. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. We utilize the sales and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

Research and development costs

R&D costs are expensed as incurred and include primarily salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems' costs; and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs and cost recoveries associated with third-party R&D arrangements, including upfront fees and milestones paid to third parties in connection with technologies that had not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 9, Collaborations.

Selling, general and administrative costs

Selling, general and administrative (SG&A) costs are composed primarily of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses; the U.S. healthcare reform federal excise fee on Branded Prescription Pharmaceutical Manufacturers and Importers; and other general and administrative costs. Advertising costs are expensed as incurred and were $674 million, $620 million and $489 million during the years ended December 31, 2018, 2017 and 2016, respectively. SG&A expenses also include costs and cost recoveries associated with marketing and promotion efforts under certain collaborative

arrangements. Net payment or reimbursement of SG&A costs is recognized when the obligations are incurred or we become entitled to the cost recovery. See Note 9, Collaborations.

Stock-based compensation

We have stock-based compensation plans under which various types of equity-based awards are granted, including restricted stock units (RSUs), performance units and stock options. The fair values of RSUs and stock option awards, which are subject only to service conditions with graded vesting, are recognized as compensation expense, generally on a straight-line basis over the service period, net of estimated forfeitures. The fair values of performance unit awards are recognized as compensation expense, generally on a straight-line basis from the grant date to the end of the performance period. See Note 5, Stock-based compensation.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate. Significant judgment is required in determining our provision for income taxes and income tax assets and liabilities, including evaluating uncertainties in the application of accounting principles and complex tax laws. Deferred income taxes are recorded for the expected tax consequences of temporary differences between the bases of assets and liabilities, as well as for loss and tax credit carryforwards for financial reporting purposes and amounts recognized for income tax purposes. We record a valuation allowance to reduce our deferred tax assets to the amount of future tax benefit that is more likely than not to be realized.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits (UTBs) is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense. See Note 7, Income taxes.

Business combinations

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method, assets acquired, including in-process research and development (IPR&D) projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with a business combination (including the assumption of an acquiree's liability arising from a business combination it consummated prior to our acquisition) are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in earnings. See Note 3, Business combinations, and Note 18, Fair value measurement.

Cash equivalents

We consider cash equivalents to be only those investments that are highly liquid, readily convertible to cash and which mature within three months from the date of purchase.

Interest-bearing securities

We consider our interest-bearing securities investment portfolio available-for-sale, and accordingly, these investments are recorded at fair value, with unrealized gains and losses recorded in Accumulated other comprehensive income (loss) (AOCI). Investments with maturities beyond one year may be classified as short-term marketable securities in the Consolidated Balance Sheets due to their highly liquid nature and because they represent the Company's investments that are available for current operations. See Note 11, Investments, and Note 18, Fair value measurement.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner that approximates the first-in, first-out method. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. See Note 12, Inventories.

Derivatives

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Consolidated Balance Sheets. The accounting for changes in the fair value of a derivative instrument depends on whether the derivative has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of

hedging relationship. For derivatives formally designated as hedges, we assess both at inception and quarterly thereafter, whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item. Our derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings. See Note 18, Fair value measurement, and Note 19, Derivative instruments.

Property, plant and equipment, net

Property, plant and equipment is recorded at historical cost, net of accumulated depreciation, amortization and, if applicable, impairment charges. We review our property, plant and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Depreciation is provided over the assets' useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms. See Note 13, Property, plant and equipment.

Goodwill and other intangible assets

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is provided over their estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note 14, Goodwill and other intangible assets.

The fair values of IPR&D projects acquired in a business combination that are not complete are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related R&D efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market the resulting products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods.

Capitalized IPR&D projects are tested for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. We consider various factors for potential impairment, including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays in obtaining marketing approval, the inability to bring a product to market and the introduction or advancement of competitors' products could result in partial or full impairment of the related intangible assets.

We perform an impairment test of goodwill annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. To date, an impairment of goodwill has not been recorded. See Note 14, Goodwill and other intangible assets.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. Certain of these proceedings are discussed in Note 20, Contingencies and commitments. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Foreign currency translation

The net assets of international subsidiaries whose local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating net assets of these subsidiaries at changing rates are recognized in AOCI. The earnings of these subsidiaries are translated into U.S. dollars using average exchange rates.

Other recently adopted pronouncements

In January 2016, the FASB issued a new accounting standard that amends the accounting and disclosures of financial instruments, including a provision requiring that equity investments (except for investments accounted for under the equity method of accounting) be measured at fair value, with changes in fair value recognized in current

earnings. With the exception of equity investments that were previously accounted for at cost, a modified-retrospective approach was used to reflect the cumulative-effect of adoption as an adjustment to Accumulated deficit as of the beginning of the fiscal year. The new standard will be applied prospectively to investments currently that were previously accounted for at cost. Upon adoption, on January 1, 2018, we recorded

an immaterial adjustment to Accumulated deficit from AOCI, which represented the net unrealized gain on all equity investments with readily determinable fair values as of December 31, 2017. The impact that this new standard has on our consolidated statements of income after adoption will depend on changes in fair values of equity securities in our portfolio in the future. See Note 11, Investments.

In October 2016, the FASB issued a new accounting standard that amends the income tax accounting guidance for intra-entity transfers of assets other than inventory. The new standard requires that entities recognize the income tax consequences of an intercompany transfer of an asset, other than inventory, in the period the transfer occurs. The current exception to defer the recognition of any tax impact on intercompany transfers of inventory until the inventory is sold to a third party remains unaffected. We adopted this standard as of January 1, 2018, and will apply it to any transaction occurring on or after the adoption date. The adoption of this standard did not have a material impact on our consolidated financial statements; however, the impact on our consolidated financial statements in future periods will depend on the facts and circumstances of future transactions.

In January 2017, the FASB issued a new accounting standard that changes the definition of a business to assist entities with the evaluation of when a set of assets acquired or disposed of should be considered a business. The new standard requires that an entity evaluate whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets; if so, the set of assets would not be considered a business. The new standard also requires that a business include at least one substantive process, and it narrows the definition of outputs. We adopted this standard as of January 1, 2018. Adoption of this new standard may result in more transactions being accounted for as asset acquisitions versus business combinations; however, the impact on our consolidated financial statements in future periods will depend on the facts and circumstances of future transactions.

In August 2017, the FASB issued a new accounting standard that amends the accounting and reporting of hedging activities, which we elected to adopt early during the second quarter of 2018. Among its provisions, the new standard (i) eliminates the separate measurement and reporting of hedge ineffectiveness and (ii) permits an entity to recognize in earnings the initial fair value of an excluded component of a hedging instrument's fair value under a systematic and rational method over the life of the derivative instrument. In accordance with the transition provisions of the new standard, the separate measurement of ineffectiveness for our cash flow hedging instruments existing as of the date of adoption is required to be eliminated through a cumulative-effect adjustment to Accumulated deficit as of January 1, 2018, the beginning of the fiscal year. In addition, certain provisions in the guidance require modifications to existing presentation and disclosure requirements on a prospective basis. The adoption of this standard did not have a material impact on our consolidated financial statements. See Note 19, Derivative instruments.

Other recent accounting pronouncements

In February 2016, the FASB issued a new accounting standard that amends the guidance for the accounting and disclosure of leases. This new standard requires that lessees recognize on the balance sheet the assets and liabilities that arise from leases, including leases classified as operating leases under current GAAP, and disclose qualitative and quantitative information about leasing arrangements. The new standard requires a modified-retrospective approach to adoption and is effective for interim and annual periods beginning on January 1, 2019. In July 2018, the FASB further amended this standard to allow for a new transition method that offers the option to use the effective date as the date of initial application. We intend to elect this alternative transition method and therefore will not adjust comparative-period financial information. In addition, we intend to elect the package of practical expedients permitted under the transition guidance of the new standard to not reassess prior conclusions related to contracts that are or that contain leases, lease classification and initial direct costs. We do not expect that this standard will have a material impact on our Consolidated Statements of Income. The primary effect of adoption will be the requirement to record the present value of lease liabilities for current operating leases and corresponding right-of-use (ROU) assets. Upon adoption, we estimate we will have additional liabilities ranging from $400 million to $450 million with corresponding ROU assets of a similar amount for lease agreements in effect as of December 31, 2018. The actual impact will depend on our lease portfolio at the time of adoption. We are currently finalizing the implementation of the lease accounting information system, documenting processes, and establishing internal controls to properly track, record and account for our lease portfolio. The new standard also provides practical expedients for the ongoing accounting. We also currently expect to elect the practical expedient to not separate lease and nonlease components for most of our asset classes.

In June 2016, the FASB issued a new accounting standard that amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the incurred-loss model with an expected-loss model. Accordingly, these financial assets will be presented at the net amount expected to be collected.

This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The new standard is effective for interim and annual periods beginning on January 1, 2020, but may be adopted earlier, beginning on January 1, 2019. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. We are currently evaluating the impact that this new standard will have on our consolidated financial statements.

2. Restructuring

In 2014, we initiated a restructuring plan to invest in continuing innovation and the launch of our new pipeline molecules, while improving our cost structure. As part of the plan, we closed facilities in Washington State and Colorado and are reducing the number of buildings we occupy at our headquarters in Thousand Oaks, California, as well as at other locations. We completed the activities associated with this restructuring plan in 2018.

Through December 31, 2018, we incurred $548 million of separation costs and other headcount-related costs for staff reductions and $261 million of net asset-related charges, which consist primarily of asset impairments, accelerated depreciation and other related costs resulting from the consolidation of our worldwide facilities. During the years ended December 31, 2018, 2017 and 2016, we incurred restructuring costs of $12 million, $88 million and $37 million, respectively. As of December 31, 2018 and 2017, the restructuring liabilities were not significant.

3. Business combinations

Kirin-Amgen, Inc.

During the first quarter of 2018, we acquired the remaining 50% ownership of Kirin-Amgen, Inc. (K-A), from Kirin Holdings Company, Limited (Kirin), making K-A a wholly owned subsidiary of Amgen. Upon its acquisition, K-A's operations have been included in our consolidated financial statements commencing on the share acquisition date. The acquisition relieved Amgen of future royalty obligations to K-A.

Prior to the share acquisition date, we owned 50% of K-A and accounted for our interest in K-A by using the equity method of accounting. See Note 10, Related party transactions.

The transaction was accounted for as a step acquisition of a business in which we were required to remeasure our existing 50% ownership interest at fair value. In addition, we were required to effectively settle our preexisting relationship with K-A, which resulted in a loss. Together the gain on the remeasurement of our existing ownership interest and the loss from the settlement of the preexisting relationship resulted in a net gain of $80 million, which was recorded in Interest and other income, net, in the Consolidated Statements of Income.

The primary means of consideration for this transaction was a payment of $780 million in cash. The aggregate share acquisition date consideration to acquire the remaining 50% ownership in K-A and the fair value of Amgen's preacquisition investment consisted of the following (in millions):

	Amounts
Total cash paid to Kirin	$ 780
Fair value of contingent consideration obligation	45
Loss on settlement of preexisting relationship	(168)
Total consideration transferred to acquire K-A	657
Fair value of Amgen's investment in K-A	825
Total acquisition date fair value	$ 1,482

In connection with this acquisition, we are obligated to make single-digit royalty payments to Kirin contingent upon sales of brodalumab. The estimated fair value of this contingent consideration obligation was $45 million as of the share acquisition date.

The fair values of assets acquired and liabilities assumed consisted of cash of $977 million, licensing rights of $470 million, deferred tax liabilities of $102 million, other assets and liabilities of $131 million and goodwill of $6 million. The estimated fair value of acquired licensing rights was determined by using a probability-weighted-income approach, which discounts expected future cash flows to present value by using a discount rate that represents the estimated rate that market participants would use to value the assets. The projected cash flows were based on certain assumptions, including estimates of future revenues and expenses and the time and resources needed to maintain the assets through commercialization. The licensing rights will be amortized over a weighted-average period of four years by using the straight-line method. The excess of the share acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $6 million was recorded as goodwill, which is not deductible for tax purposes. The $131 million in other assets and liabilities represents primarily receivables for royalties earned by K-A but not yet received, offset partially by payables representing R&D expenses incurred but not yet reimbursed by K-A.

Pro forma results of operations for this acquisition have not been presented because this acquisition is not material to our consolidated results of operations.

4. Revenues

We operate in one business segment: human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Revenues by product and by geographic area, based on customers' locations, are presented below. Rest-of-world (ROW) revenues relate to products that are sold principally in Europe.

Revenues were as follows (in millions):

	Year ended December 31, 2018		
	US	ROW	Total
Enbrel® (etanercept)	$ 4,807	$ 207	$ 5,014
Neulasta® (pegfilgrastim)	3,866	609	4,475
Prolia® (denosumab)	1,500	791	2,291
Aranesp® (darbepoetin alfa)	942	935	1,877
XGEVA® (denosumab)	1,338	448	1,786
Sensipar® / Mimpara® (cinacalcet)	1,436	338	1,774
EPOGEN® (epoetin alfa)	1,010	—	1,010
Other products	2,530	1,776	4,306
Total product sales[1]	17,429	5,104	22,533
Other revenues	929	285	1,214
Total revenues[2]	$ 18,358	$ 5,389	$ 23,747

	Year ended December 31, 2017		
	US	ROW	Total
ENBREL	$ 5,206	$ 227	$ 5,433
Neulasta®	3,931	603	4,534
Aranesp®	1,114	939	2,053
Prolia®	1,272	696	1,968
Sensipar® / Mimpara®	1,374	344	1,718
XGEVA®	1,157	418	1,575
EPOGEN®	1,096	—	1,096
Other products	1,981	1,437	3,418
Total product sales[1]	17,131	4,664	21,795
Other revenues	898	156	1,054
Total revenues[2]	$ 18,029	$ 4,820	$ 22,849

	Year ended December 31, 2016		
	US	ROW	Total
ENBREL	$ 5,719	$ 246	$ 5,965
Neulasta®	3,925	723	4,648
Aranesp®	1,082	1,011	2,093
Prolia®	1,049	586	1,635
Sensipar® / Mimpara®	1,240	342	1,582
XGEVA®	1,115	414	1,529
EPOGEN®	1,282	—	1,282
Other products	1,913	1,245	3,158
Total product sales[1]	17,325	4,567	21,892
Other revenues	1,001	98	1,099
Total revenues[2]	$ 18,326	$ 4,665	$ 22,991

(1) Hedging gains and losses, which are included in product sales, were not material for the years ended December 31, 2018 and 2017. For the year ended December 31, 2016, hedging gains were $308 million.

(2) Prior-period amounts are not adjusted under the modified-retrospective method of adoption of the new revenue recognition accounting standard.

5. Stock-based compensation

Our Amended and Restated 2009 Equity Incentive Plan (the Amended 2009 Plan) authorizes for issuance to employees of Amgen, employees of Amgen subsidiaries and nonemployee members of our Board of Directors shares of our common stock pursuant to grants of equity-based awards, including RSUs, stock options and performance units. The pool of shares available under the Amended 2009 Plan is reduced by one share for each stock option granted and by 1.9 shares for other types of awards granted, including RSUs and performance units (full-value awards). In general, if any shares subject to an award granted under the Amended 2009 Plan expire or become forfeited, terminated or canceled without the issuance of shares, the shares subject to such awards are added back into the authorized pool on the same basis that they were removed. In addition, under the Amended 2009 Plan, shares withheld to pay for minimum statutory tax obligations with respect to full-value awards are added back into the authorized pool on the basis of 1.9 shares. As of December 31, 2018, the Amended 2009 Plan provides for future grants and/or issuances of up to 32 million shares of our common stock. Stock-based awards under our employee compensation plans are made with newly issued shares reserved for this purpose.

The following table reflects the components of stock-based compensation expense recognized in our Consolidated Statements of Income (in millions):

	Years ended December 31,		
	2018	2017	2016
RSUs	$ 165	$ 174	$ 177
Performance units	117	133	123
Stock options	29	22	11
Total stock-based compensation expense, pretax	311	329	311
Tax benefit from stock-based compensation expense	(67)	(118)	(112)
Total stock-based compensation expense, net of tax	$ 244	$ 211	$ 199

Restricted stock units and stock options

Eligible employees generally receive an annual grant of RSUs and, for certain executive-level employees, stock options, with the size and type of award generally determined by the employee's salary grade and performance level. In 2016, we reinstated the practice of granting stock options to eligible employees annually, which had been suspended from 2012 through 2015. In addition, certain management and professional-level employees typically receive RSU grants upon commencement of employment. Nonemployee members of our Board of Directors also receive an annual grant of RSUs.

Our RSU and stock option grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including upon death, disability, termination in connection with a change in control and the retirement of employees who meet certain service and/or age requirements. RSUs and stock options generally vest in equal amounts on the second, third and fourth anniversaries of the grant date. RSUs accrue dividend equivalents, which are typically payable in shares, only when and to the extent the underlying RSUs vest and are issued to the recipient.

Restricted stock units

The grant date fair value of an RSU equals the closing price of our common stock on the grant date, as RSUs accrue dividend equivalents during their vesting period. The weighted-average grant date fair values of RSUs granted during the years ended December 31, 2018, 2017 and 2016, were $179.18, $163.99 and $156.76, respectively.

The following table summarizes information regarding our RSUs:

	Year ended December 31, 2018	
	Units (in millions)	Weighted-average grant date fair value
Balance nonvested at December 31, 2017	3.4	$ 155.11
Granted	1.2	$ 179.18
Vested	(1.2)	$ 142.82

Forfeited	(0.3)	$	163.36
Balance nonvested at December 31, 2018	3.1	$	168.11

The total grant date fair values of RSUs that vested during the years ended December 31, 2018, 2017 and 2016, were $167 million, $182 million and $193 million, respectively.

As of December 31, 2018, there was $304 million of unrecognized compensation cost related to nonvested restricted stock units and unvested stock options, which is expected to be recognized over a weighted-average period of 1.7 years.

Stock options

The exercise price of stock options is set as the closing price of our common stock on the grant date, and the related number of shares granted is fixed at that point in time. Awards expire 10 years from the date of grant. We use the Black–Scholes option valuation model to estimate the grant date fair value of stock options.

The weighted-average assumptions used in the option valuation model and the resulting weighted-average grant date fair values of stock options granted were as follows:

	Years ended December 31,		
	2018	2017	2016
Closing price of our common stock on grant date	$ 177.46	$ 162.60	$ 156.35
Expected volatility (average of implied and historical volatility)	24.6 %	22.7 %	24.3 %
Expected life (in years)	5.8	5.8	5.8
Risk-free interest rate	2.8 %	2.1 %	1.5 %
Expected dividend yield	2.9 %	2.8 %	2.6 %
Fair value of stock options granted	$ 34.60	$ 27.54	$ 27.55

The following table summarizes information regarding our stock options:

	Year ended December 31, 2018			
	Options (in millions)	Weighted-average exercise price	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in millions)
Balance unexercised at December 31, 2017	4.0	$ 127.08		
Granted	1.2	$ 177.46		
Exercised	(0.5)	$ 76.68		
Expired/forfeited	(0.3)	$ 163.79		
Balance unexercised at December 31, 2018	4.4	$ 143.57	7.0	$ 225
Vested or expected to vest at December 31, 2018	4.2	$ 142.09	6.9	$ 220
Exercisable at December 31, 2018	1.2	$ 84.01	3.3	$ 135

The total intrinsic values of options exercised during the years ended December 31, 2018, 2017 and 2016, were $53 million, $60 million and $102 million, respectively. The actual tax benefits realized from tax deductions from option exercises during the years ended December 31, 2018, 2017 and 2016, were $12 million, $21 million and $37 million, respectively.

Performance units

Certain management-level employees also receive annual grants of performance units, which give the recipient the right to receive common stock that is contingent upon achievement of specified preestablished goals over the performance period, which is generally three years. The performance goals for the units granted during the years ended December 31, 2018, 2017 and 2016, which are accounted for as equity awards, are based on (i) Amgen's stockholder return compared with a comparator group of companies, which are considered market conditions and are therefore reflected in the grant date fair values of the units, and (ii) Amgen's stand-alone financial performance measures, which are considered performance conditions. The expense recognized for awards is based on the grant date fair value of a unit multiplied by the number of units expected to be earned with respect to the related performance conditions, net of estimated forfeitures. Depending on the outcome of these performance goals, a

recipient may ultimately earn a number of units greater or less than the number of units granted. Shares of our common stock are issued on a one-for-one basis for each performance unit earned. In general, performance unit awards vest at the end of the performance period. The performance award program provides for accelerated or continued vesting in certain circumstances as defined in the plan, including upon death, disability, a change in control and retirement of employees who meet certain service and/or age

requirements. Performance units accrue dividend equivalents that are typically payable in shares only when and to the extent the underlying performance units vest and are issued to the recipient, including with respect to market and performance conditions that affect the number of performance units earned.

We use a payout simulation model to estimate the grant date fair value of performance units. The weighted-average assumptions used in this model and the resulting weighted-average grant date fair values of performance units granted were as follows:

	Years ended December 31,		
	2018	2017	2016
Closing price of our common stock on grant date	$ 177.93	$ 162.60	$ 156.35
Volatility	23.8 %	25.9 %	25.8 %
Risk-free interest rate	2.6 %	1.4 %	0.9 %
Fair value of units granted	$ 189.21	$ 178.87	$ 170.56

The payout simulation model assumes correlations of returns of the stock prices of our common stock and the common stocks of the comparator groups of companies and stock price volatilities of the comparator groups of companies to simulate stockholder returns over the performance periods and their resulting impact on the payout percentages based on the contractual terms of the performance units.

As of December 31, 2018 and 2017, 2.0 million and 2.2 million performance units were outstanding with weighted-average grant date fair values of $180.12 and $177.16 per unit, respectively. During the year ended December 31, 2018, 0.8 million performance units with a weighted-average grant date fair value of $189.21 were granted, and 0.2 million performance units with a weighted-average grant date fair value of $177.95 were forfeited.

The total fair values of performance units that vested during the years ended December 31, 2018, 2017 and 2016 were $133 million, $219 million and $347 million, respectively, based on the number of performance units earned multiplied by the closing stock price of our common stock on the last day of the performance period.

As of December 31, 2018, there was $131 million of unrecognized compensation cost, which is expected to be recognized over a weighted-average period of one year.

6. Defined contribution plan

The Company has defined contribution plans to which employees of the Company and participating subsidiaries may defer compensation for income tax purposes. Participants are eligible to receive matching contributions based on their contributions, in addition to other Company contributions. Defined contribution plan expenses were $173 million, $196 million and $174 million for the years ended December 31, 2018, 2017 and 2016, respectively.

7. Income taxes

On December 22, 2017, the United States enacted major tax reform legislation, Public Law No. 115-97, commonly referred to as the Tax Cuts and Jobs Act (2017 Tax Act). The 2017 Tax Act imposes a repatriation tax on accumulated earnings of foreign subsidiaries, imposes a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We have completed our accounting for the tax effects of the 2017 Tax Act, including the repatriation tax, the net deferred tax remeasurement and the impact on our UTBs. None of the adjustments we made to our provisional amounts were material to our consolidated financial statements.

Income before income taxes included the following (in millions):

	Years ended December 31,		
	2018	2017	2016
Domestic	$ 4,856	$ 4,436	$ 4,478
Foreign	4,689	5,161	4,685
Total income before income taxes	$ 9,545	$ 9,597	$ 9,163

The provision for income taxes included the following (in millions):

	Years ended December 31,		
	2018	2017	2016
Current provision:			
Federal	$ 1,270	$ 8,615	$ 984
State	17	5	65
Foreign	227	275	176
Total current provision	1,514	8,895	1,225
Deferred (benefit) provision:			
Federal	(317)	(1,120)	372
State	(7)	—	(69)
Foreign	(39)	(157)	(87)
Total deferred (benefit) provision	(363)	(1,277)	216
Total provision for income taxes	$ 1,151	$ 7,618	$ 1,441

Deferred income taxes reflect the tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards and the tax effects of net operating loss (NOL) carryforwards. Significant components of our deferred tax assets and liabilities were as follows (in millions):

	December 31,	
	2018	2017
Deferred income tax assets:		
NOL and credit carryforwards	$ 810	$ 812
Accrued expenses	428	362
Expenses capitalized for tax	185	155
Stock-based compensation	95	99
Other	174	154
Total deferred income tax assets	1,692	1,582
Valuation allowance	(509)	(497)
Net deferred income tax assets	1,183	1,085
Deferred income tax liabilities:		
Acquired intangible assets	(1,509)	(1,748)
Debt	(184)	(184)
Other	(267)	(240)
Total deferred income tax liabilities	(1,960)	(2,172)
Total deferred income taxes, net	$ (777)	$ (1,087)

Valuation allowances are provided to reduce the amounts of our deferred tax assets to an amount that is more likely than not to be realized based on an assessment of positive and negative evidence, including estimates of future taxable income necessary to realize future deductible amounts.

The valuation allowance increased in 2018 due primarily to the Company's expectation that some state R&D credits will not be utilized.

As of December 31, 2018, we had $20 million of federal tax credit carryforwards available to reduce future federal income taxes and have provided no valuation allowance for those federal tax credit carryforwards. The federal tax credit carryforwards expire between 2026 and 2035. We had $556 million of state tax credit carryforwards available to reduce future state income taxes and have provided a valuation allowance for $444 million of those state

tax credit carryforwards. A portion of the state credits for which no valuation allowance has been provided will expire between 2022 and 2024.

As of December 31, 2018, we had $145 million of federal NOL carryforwards available to reduce future federal income taxes and have provided a valuation allowance for $6 million of those federal NOL carryforwards. The federal NOL carryforwards, for which no valuation allowance has been provided, expire between 2020 and 2035. We had $287 million of state NOL carryforwards available to reduce future state income taxes and have provided a valuation allowance for $263 million of those state NOL carryforwards. The state NOLs for which no valuation allowance has been provided expire between 2019 and 2032. We had $1.8 billion of foreign NOL carryforwards available to reduce future foreign income taxes and have provided a valuation allowance for $485 million of those foreign NOL carryforwards. For the foreign NOLs with no valuation allowance provided, $620 million has no expiry; and the remainder will expire between 2019 and 2024.

The reconciliations of the total gross amounts of UTBs (excluding interest, penalties, foreign tax credits and the federal tax benefit of state taxes related to UTBs) were as follows (in millions):

	Years ended December 31,		
	2018	2017	2016
Beginning balance	$ 2,953	$ 2,543	$ 2,114
Additions based on tax positions related to the current year	173	447	425
Additions based on tax positions related to prior years	13	1	18
Reductions for tax positions of prior years	(17)	(5)	(7)
Reductions for expiration of statute of limitations	—	(5)	—
Settlements	(61)	(28)	(7)
Ending balance	$ 3,061	$ 2,953	$ 2,543

Substantially all of the UTBs as of December 31, 2018, if recognized, would affect our effective tax rate. During the year ended December 31, 2018, we effectively settled various examinations with state tax authorities for prior tax years. As a result of these developments, we remeasured our UTBs accordingly.

Interest and penalties related to UTBs are included in our provision for income taxes. During the years ended December 31, 2018, 2017 and 2016, we recognized $137 million, $56 million and $125 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. As of December 31, 2018 and 2017, accrued interest and penalties associated with UTBs were $469 million and $332 million, respectively.

The reconciliations between the federal statutory tax rate applied to income before income taxes and our effective tax rate were as follows:

	Years ended December 31,		
	2018	2017	2016
Federal statutory tax rate	21.0 %	35.0 %	35.0 %
2017 Tax Act, net repatriation tax	— %	70.7 %	— %
Foreign earnings	(4.3 %)	(15.8 %)	(15.5 %)
2017 Tax Act, net deferred tax remeasurement	— %	(6.9 %)	— %
Credits, Puerto Rico Excise Tax	(2.5 %)	(2.2 %)	(2.3 %)
2017 Tax Act, net impact on intercompany sales	(1.8 %)	— %	— %
Interest on uncertain tax positions	1.2 %	0.6 %	0.5 %
Credits, primarily federal R&D	(0.8 %)	(0.6 %)	(0.7 %)
Share-based payments	(0.2 %)	(0.7 %)	(1.3 %)
Other, net	(0.5 %)	(0.7 %)	— %

Effective tax rate	12.1 %	79.4 %	15.7 %

The effective tax rate for the year ended December 31, 2018 differs from the federal statutory rate due primarily to impacts of the jurisdictional mix of income and expenses. The effective tax rate for 2017 differs from the federal statutory rate primarily as a result of the 2017 Tax Act. The effective tax rate for 2016 differs from the federal statutory rate primarily as a result of indefinitely invested earnings of our foreign operations. Substantially all of the benefit to our effective tax rate from foreign earnings results from the Company's operations conducted in Puerto Rico, a territory of the United States that is treated as a foreign

jurisdiction for U.S. tax purposes and is subject to tax incentive grants through 2035; these earnings are also subject to U.S. tax at a reduced 10.5% rate.

The U.S. territory of Puerto Rico imposes an excise tax on the gross intercompany purchase price of goods and services from our manufacturer in Puerto Rico. The rate of 4% is effective through December 31, 2027. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in cost of sales when the related products are sold. For U.S. income tax purposes, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes when the excise tax is incurred.

Income taxes paid during the years ended December 31, 2018, 2017 and 2016, were $1.9 billion, $1.5 billion and $1.1 billion, respectively.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by the tax authorities in those jurisdictions. Significant disputes may arise with authorities involving issues of the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and the interpretation of the relevant facts. As previously disclosed, we received a Revenue Agent Report (RAR) from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Final resolution of this complex matter is not likely within the next 12 months and could have a material impact on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009. In addition, we are currently under examination by a number of other state and foreign tax jurisdictions.

8. Earnings per share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which include primarily shares that may be issued under our stock option, restricted stock and performance unit award programs, as determined by using the treasury stock method (collectively, dilutive securities).

The computations for basic and diluted EPS were as follows (in millions, except per-share data):

	Years ended December 31,		
	2018	2017	2016
Income (Numerator):			
Net income for basic and diluted EPS	$ 8,394	$ 1,979	$ 7,722
Shares (Denominator):			
Weighted-average shares for basic EPS	661	731	748
Effect of dilutive securities	4	4	6
Weighted-average shares for diluted EPS	665	735	754
Basic EPS	$ 12.70	$ 2.71	$ 10.32
Diluted EPS	$ 12.62	$ 2.69	$ 10.24

For each of the three years ended December 31, 2018, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

9. Collaborations

A collaborative arrangement is a contractual arrangement that involves a joint operating activity. Such arrangements involve two or more parties that are both (i) active participants in the activity and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for nonrefundable upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration arrangements are performed with no guarantee of either technological or commercial success, and each is unique in nature. See Note 1, Summary of significant accounting policies, for additional discussion of revenues recognized for these types of arrangements. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line items in the consolidated statements of income, net of any payments due to or reimbursements due from our collaboration partners, with such reimbursements being recognized at the time the party becomes obligated to pay. Our significant arrangements are discussed below.

Novartis AG

In April 2017, we expanded our existing migraine collaboration with Novartis AG (Novartis). In the United States, Amgen and Novartis jointly develop and collaborate on the commercialization of Aimovig® (erenumab-aooe). Amgen, as the principal, recognizes product sales of Aimovig® in the United States, shares U.S. commercialization costs with Novartis and pays Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig® and other specified migraine programs. Novartis pays Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories and funds a portion of global R&D expenses. In addition, Novartis will make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds are achieved with respect to Aimovig® in the United States. Amgen manufactures and supplies Aimovig® worldwide.

The migraine collaboration will continue for the commercial lives of the products unless terminated in accordance with its terms.

During the year ended December 31, 2018, net costs paid to Novartis for migraine products were $44 million and were recorded primarily in Selling, general and administrative expense in the Consolidated Statements of Income. During the years ended December 31, 2017 and 2016, net costs recovered from Novartis for the migraine products were $124 million and $33 million, respectively, and were recorded primarily in Research and development expense in the Consolidated Statements of Income. During the year ended December 31, 2018, royalties due to Novartis for the migraine products were $43 million and were recorded in Cost of sales in the Consolidated Statements of Income. As a result of certain regulatory and commercial events, we received milestone payments from Novartis of $295 million and $60 million during the years ended December 31, 2018 and 2017, respectively, which were recorded in Other revenues in the Consolidated Statements of Income.

UCB

We are in a collaboration with UCB for the development and commercialization of EVENITY™ (romosozumab). Under our collaboration, UCB has the rights to lead commercialization for EVENITY™ for all indications in Europe, China (excluding Hong Kong) and Brazil. All other territories have been allocated to Amgen. Generally, development costs and future worldwide commercialization profits and losses related to the collaboration after accounting for expenses are shared equally. The collaboration agreement will continue in effect unless terminated earlier in accordance with its terms. During the years ended December 31, 2018, 2017 and 2016, net costs recovered from UCB were not material and were recorded primarily in Research and development expense in the Consolidated Statements of Income.

Bayer HealthCare Pharmaceuticals Inc.

We are in a collaboration with Bayer HealthCare Pharmaceuticals Inc. (Bayer) to jointly develop and commercialize Nexavar® (sorafenib) worldwide, except in Japan. The rights to develop and market Nexavar® in Japan are reserved to Bayer. Nexavar® is currently marketed and sold in more than 100 countries around the world for the treatment of unresectable liver cancer and advanced kidney cancer. In the United States, Nexavar® is also approved for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

In 2015, we amended the terms of our collaboration agreement with Bayer, which terminated the co-promotion agreement in the United States and transferred all U.S. operational responsibilities to Bayer, including commercial and medical affairs activities. Prior to the termination of the co-promotion agreement, we co-promoted Nexavar® with Bayer and shared equally in the profits or losses in the United States. In lieu of this profit share, Bayer now pays Amgen a royalty on U.S. sales of Nexavar® at a percentage rate in the high 30s. Amgen no longer contributes sales force personnel or medical liaisons to support Nexavar®

in the United States. There are no changes to the global R&D or non-U.S. profit share arrangements in the original agreement, as discussed below.

In all countries outside the United States, excluding Japan, Bayer manages all commercialization activities and incurs all of the sales and marketing expenditures and mutually agreed R&D expenses, for which we continue to reimburse Bayer for half. In these countries, we continue to receive 50% of net profits on sales of Nexavar® after deducting certain Bayer-related costs.

The agreement with Bayer will terminate at the later of the date when patents expire that were issued in connection with product candidates discovered under the agreement or on the last day that we or Bayer market or sell products commercialized under the agreement anywhere in the world. Patents related to Nexavar® begin to expire in 2020.

During the years ended December 31, 2018, 2017 and 2016, Amgen recorded Nexavar® net profits of $164 million, $161 million and $167 million, respectively, which were recognized as Other revenues in the Consolidated Statements of Income. During the years ended December 31, 2018, 2017 and 2016, Amgen recorded royalty income of $91 million, $133 million and $137 million, respectively, in Other revenues in the Consolidated Statements of Income, pursuant to the 2015 amendment to the collaboration agreement. Net R&D expenses related to the agreement were not material for the years ended December 31, 2018, 2017 and 2016.

Other

In addition to the collaborations discussed above, we have various others that are not individually significant to our business at this time. Pursuant to the terms of those agreements, we may be required to pay or we may receive additional amounts upon the achievement of various development and commercial milestones, which in the aggregate could be significant. We may also incur or have reimbursed to us significant R&D costs if the related product candidate were to advance to late-stage clinical trials. In addition, if any products related to these collaborations are approved for sale, we may be required to pay or we may receive significant royalties on future sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurrence.

10. Related party transactions

As of December 31, 2017, we owned a 50% interest in K-A, a corporation formed in 1984 with Kirin for the development and commercialization of certain products based on advanced biotechnology. All of our rights to manufacture and market certain products including pegfilgrastim, filgrastim, darbepoetin alfa, recombinant human erythropoietin and romiplostim are pursuant to exclusive licenses from K-A, which we currently market under the brand names Neulasta®, NEUPOGEN® (filgrastim)/GRANULOKINE®, Aranesp®, EPOGEN® and Nplate® (romiplostim), respectively. During the first quarter of 2018, we acquired the remaining 50% ownership of K-A from Kirin, making K-A a wholly owned subsidiary of Amgen. The transaction was accounted for as a business combination. K-A's results of operations are now included in our consolidated financial statements, and as a result, transactions between us and K-A are eliminated in consolidation. See Note 3, Business combinations. License agreements with Kirin and Johnson & Johnson (J&J) remain in place.

Prior to the share acquisition, we accounted for our interest in K-A using the equity method and included our share of K-A's profits or losses in Selling, general and administrative expense in the Consolidated Statements of Income. Our share of K-A's profits was insignificant for the period January 1, 2018 through the 2018 share acquisition date. For the years ended December 31, 2017 and 2016, our share of K-A's profits was $68 million and $58 million, respectively. The carrying value of our equity method investment in K-A was $570 million as of December 31, 2017, and is included in Other assets in the Consolidated Balance Sheets.

K-A's revenues consist of royalty income related to its licensed technology rights. Prior to the share acquisition, K-A received royalty income from us. K-A also received and continues to receive royalty income from Kirin and J&J under separate product license contracts for certain geographic areas outside the United States. Royalties earned by K-A from us were insignificant for the period January 1, 2018 through the 2018 share acquisition date. During the years ended December 31, 2017 and 2016, K-A earned royalties from us of $221 million and $239 million, respectively. These amounts are included in Cost of sales in the Consolidated Statements of Income.

K-A's expenses consist primarily of costs related to R&D activities conducted on its behalf by us through the 2018 share acquisition and by Kirin. Payment for these services is based on negotiated rates. Revenues from K-A for certain R&D activities performed on K-A's behalf were insignificant for the period January 1, 2018 through the 2018 share acquisition date. During the years ended December 31, 2017 and 2016, we earned revenues from K-A of $28

million and $31 million, respectively, for certain R&D activities performed on K-A's behalf. These amounts were recognized as Other revenues in the Consolidated Statements of

Income. Cost recoveries from K-A recorded during the period January 1, 2018 through the 2018 share acquisition date and the years ended December 31, 2017 and 2016, were insignificant. These amounts are included in Research and development expense in the Consolidated Statements of Income.

As of December 31, 2017, we owed K-A $80 million, which is included in Accrued liabilities in the Consolidated Balance Sheets.

11. Investments

Available-for-sale investments

The amortized cost, gross unrealized gains, gross unrealized losses and fair values of available-for-sale investments by type of security were as follows (in millions):

Types of securities as of December 31, 2018	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 2,710	$ —	$ (47)	$ 2,663
U.S. Treasury bills	8,191	—	—	8,191
Other government-related debt securities:				
U.S.	112	—	(2)	110
Foreign and other	972	1	(41)	932
Corporate debt securities:				
Financial	2,778	—	(81)	2,697
Industrial	2,603	—	(99)	2,504
Other	583	—	(21)	562
Residential-mortgage-backed securities	1,458	—	(36)	1,422
Other mortgage- and asset-backed securities	483	—	(14)	469
Money market mutual funds	5,659	—	—	5,659
Other short-term interest-bearing securities	3,515	—	—	3,515
Total available-for-sale investments	$ 29,064	$ 1	$ (341)	$ 28,724

Types of securities as of December 31, 2017	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 8,313	$ 1	$ (72)	$ 8,242
Other government-related debt securities:				
U.S.	225	—	(2)	223
Foreign and other	2,415	18	(11)	2,422
Corporate debt securities:				
Financial	10,089	17	(34)	10,072
Industrial	9,688	34	(52)	9,670
Other	1,393	3	(6)	1,390
Residential-mortgage-backed securities	2,198	—	(30)	2,168
Other mortgage- and asset-backed securities	2,312	—	(15)	2,297
Money market mutual funds	3,245	—	—	3,245
Other short-term interest-bearing securities	1,440	—	—	1,440
Total interest-bearing securities	41,318	73	(222)	41,169
Equity securities	135	14	—	149
Total available-for-sale investments	$ 41,453	$ 87	$ (222)	$ 41,318

The fair values of available-for-sale investments by location in the Consolidated Balance Sheets were as follows (in millions):

Consolidated Balance Sheets locations	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 6,365	$ 3,291
Marketable securities	22,359	37,878
Other assets	—	149
Total available-for-sale investments	$ 28,724	$ 41,318

Cash and cash equivalents in the above table excludes bank account cash of $580 million and $509 million as of December 31, 2018 and 2017, respectively. Other assets as of December 31, 2017, consisted of equity securities, which are no longer classified as available-for-sale.

As a result of the adoption of the new accounting standard related to the classification and measurement of financial instruments on January 1, 2018, equity investments (except for investments accounted for under the equity method of accounting) are now measured at fair value, with changes in fair value recognized in earnings. These investments were previously measured at fair value, with changes in fair value recognized in AOCI. Accordingly, these securities are no longer classified as available-for-sale and their presentation is not comparable to the presentation as of December 31, 2017. See Equity securities, discussed below, and Note 1, Summary of significant accounting policies.

The fair values of available-for-sale interest-bearing security investments by contractual maturity, except for mortgage- and asset-backed securities that do not have a single maturity date, were as follows (in millions):

Contractual maturities	December 31, 2018	December 31, 2017
Maturing in one year or less	$ 17,424	$ 6,733
Maturing after one year through three years	3,356	12,820
Maturing after three years through five years	5,168	13,836
Maturing after five years through ten years	885	3,263
Maturing after ten years	—	52
Mortgage- and asset-backed securities	1,891	4,465
Total interest-bearing securities	$ 28,724	$ 41,169

For the years ended December 31, 2018, 2017 and 2016, realized gains on interest-bearing securities were $29 million, $147 million and $304 million, respectively, and realized losses on interest-bearing securities were $394 million, $213 million and $367 million, respectively. Realized gains and losses on interest-bearing securities are recorded in Interest and other income, net, in the Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

The fair values and gross unrealized losses of available-for-sale investments in an unrealized loss position aggregated by type and length of time that the securities have been in a continuous loss position were as follows (in millions):

	Less than 12 months		12 months or more	
Types of securities as of December 31, 2018	**Fair values**	**Unrealized losses**	**Fair values**	**Unrealized losses**
U.S. Treasury notes	$ 1,219	$ (21)	$ 1,444	$ (26)
Other government-related debt securities:				
U.S.	—	—	110	(2)
Foreign and other	631	(31)	240	(10)
Corporate debt securities:				
Financial	1,968	(59)	718	(22)
Industrial	1,898	(81)	529	(18)
Other	529	(20)	28	(1)
Residential-mortgage-backed securities	576	(14)	840	(22)
Other mortgage- and asset-backed securities	17	—	451	(14)
Total	$ 6,838	$ (226)	$ 4,360	$ (115)

	Less than 12 months		12 months or more	
Types of securities as of December 31, 2017	**Fair values**	**Unrealized losses**	**Fair values**	**Unrealized losses**
U.S. Treasury notes	$ 7,728	$ (70)	$ 195	$ (2)
Other government-related debt securities:				
U.S.	188	(1)	34	(1)
Foreign and other	1,163	(9)	115	(2)
Corporate debt securities:				
Financial	5,928	(28)	462	(6)
Industrial	5,760	(43)	612	(9)
Other	868	(4)	117	(2)
Residential-mortgage-backed securities	1,838	(24)	276	(6)
Other mortgage- and asset-backed securities	1,777	(12)	250	(3)
Total	$ 25,250	$ (191)	$ 2,061	$ (31)

The primary objective of our investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

We review our available-for-sale investments for other-than-temporary declines in fair value below our cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. The evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below our cost basis, as well as adverse conditions related specifically to the security such as any changes to the credit rating of the security and the intent to sell or whether we will more likely than not be required to sell the security before recovery of its amortized cost basis. Our assessment of whether a security is other-than-temporarily impaired could change in the future based on new developments or changes in assumptions related to that particular security. As of December 31, 2018, unrealized losses on available-for-sale investments were due primarily to higher interest rates on that date than at the time the securities were purchased. As of December 31, 2018 and 2017, we believe the cost bases for our available-for-sale investments were recoverable in all material respects.

Equity securities

We held investments in equity securities with readily determinable fair values of $176 million and $149 million as of December 31, 2018 and 2017, respectively, which are included in Other assets in the Consolidated Balance Sheets. As a result of the adoption of the new accounting standard related to the classification and measurement of financial instruments on January 1, 2018, equity investments (except for investments accounted for under the equity method of accounting) are now measured at fair value, with changes in fair value recognized in earnings. These investments were previously measured at fair value, with changes in fair value recognized in AOCI. Accordingly, these securities are no longer classified as available-for-sale and their presentation is not comparable to the presentation as of December 31, 2017. See Available-for-sale investments, discussed above, and Note 1, Summary of significant accounting policies. Gains and losses recognized on equity securities with readily determinable fair values, including gains and losses recognized on sales, were not material for the years ended December 31, 2018, 2017 and 2016.

We held investments in equity securities without readily determinable fair values of $222 million and $95 million as of December 31, 2018 and 2017, respectively, which are included in Other assets in the Consolidated Balance Sheets. Adjustments to the carrying values of these securities were not material for the years ended December 31, 2018, 2017 and 2016.

Limited partnership investments

We held limited partnership investments of $285 million and $213 million as of December 31, 2018 and 2017, respectively, which are included in Other assets in the Consolidated Balance Sheets. These investments are measured by using the net asset values of the underlying investments as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of December 31, 2018, unfunded additional commitments to be made during the next several years for these investments were not material. Gains and losses recognized on our limited partnership investments were not material for the years ended December 31, 2018, 2017 and 2016.

12. Inventories

Inventories consisted of the following (in millions):

	December 31,	
	2018	2017
Raw materials	$ 257	$ 232
Work in process	1,660	1,668
Finished goods	1,023	934
Total inventories	$ 2,940	$ 2,834

13. Property, plant and equipment

Property, plant and equipment consisted of the following (dollar amounts in millions):

		December 31,	
	Useful life (in years)	2018	2017
Land	—	$ 265	$ 283
Buildings and improvements	10-40	3,616	3,507
Manufacturing equipment	8-12	2,418	2,372
Laboratory equipment	8-12	1,174	1,179
Capitalized software	3-5	1,124	1,150
Other	3-15	3,204	3,254
Construction in progress	—	953	834
Property, plant and equipment, gross		12,754	12,579
Less accumulated depreciation and amortization		(7,796)	(7,590)
Property, plant and equipment, net		$ 4,958	$ 4,989

During the years ended December 31, 2018, 2017 and 2016, we recognized depreciation and amortization expense associated with our property, plant and equipment of $630 million, $604 million and $619 million, respectively.

Geographic information

Certain geographic information with respect to property, plant and equipment, net (long-lived assets), was as follows (in millions):

	December 31,	
	2018	2017
United States	$ 2,373	$ 2,349
Puerto Rico	1,476	1,527
ROW	1,109	1,113
Total property, plant and equipment, net	$ 4,958	$ 4,989

14. Goodwill and other intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows (in millions):

	Years ended December 31,	
	2018	2017
Beginning balance	$ 14,761	$ 14,751
Addition from K-A acquisition	6	—
Currency translation adjustments	(68)	10
Ending balance	$ 14,699	$ 14,761

Other intangible assets

Other intangible assets consisted of the following (in millions):

	December 31,					
	2018			2017		
	Gross carrying amounts	Accumulated amortization	Other intangible assets, net	Gross carrying amounts	Accumulated amortization	Other intangible assets, net
Finite-lived intangible assets:						
Developed-product-technology rights	$ 12,573	$ (7,479)	$ 5,094	$ 12,589	$ (6,796)	$ 5,793
Licensing rights	3,772	(2,032)	1,740	3,275	(1,601)	1,674
Marketing-related rights	1,297	(1,019)	278	1,319	(920)	399
R&D technology rights	1,148	(872)	276	1,161	(804)	357
Total finite-lived intangible assets	18,790	(11,402)	7,388	18,344	(10,121)	8,223
Indefinite-lived intangible assets:						
IPR&D	55	—	55	386	—	386
Total other intangible assets	$ 18,845	$ (11,402)	$ 7,443	$ 18,730	$ (10,121)	$ 8,609

Developed-product-technology rights consist of rights related to marketed products acquired in business combinations. Licensing rights consist primarily of contractual rights acquired in business combinations to receive future milestone, royalty and profit-sharing payments; capitalized payments to third parties for milestones related to regulatory approvals to commercialize products; and upfront payments associated with royalty obligations for marketed products. Licensing rights increased in 2018 due to the K-A share acquisition. See Note 3, Business combinations. Marketing-related rights assets consist primarily of rights related to the sale and distribution of marketed products. R&D technology rights consist of technology used in R&D with alternative future uses.

IPR&D consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. During 2018, we discontinued the internal development of a non-key program, resulting in an impairment charge of $330 million, which was recognized in Other operating expenses in the Consolidated Statements of Income and included in Other items, net, in the Consolidated Statements of Cash Flows.

All IPR&D projects have major risks and uncertainties associated with the timely and successful completion of the development and commercialization of product candidates, including our ability to confirm safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not permitted to market a human therapeutic without obtaining regulatory approvals, and such approvals require the completion of clinical trials that demonstrate that a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans as well as competitive product launches, affect the revenues a product can generate. Consequently, the eventual realized value, if any, of acquired IPR&D projects may vary from their estimated fair values. We review IPR&D projects for impairment annually, whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable and upon the establishment of technological feasibility or regulatory approval.

During the years ended December 31, 2018, 2017 and 2016, we recognized amortization expenses associated with our finite-lived intangible assets of $1.3 billion, $1.3 billion and $1.5 billion, respectively. Amortization of intangible assets is included primarily in Cost of sales in the Consolidated Statements of Income. The total estimated amortization expenses for our finite-lived intangible assets for each of the next five years are $1.3 billion, $1.2 billion, $1.0 billion, $0.9 billion and $0.9 billion in 2019, 2020, 2021, 2022 and 2023, respectively.

15. Accrued liabilities

Accrued liabilities consisted of the following (in millions):

	December 31,	
	2018	2017
Sales deductions	$ 3,170	$ 2,247
Employee compensation and benefits	1,001	816
Dividends payable	914	953
Sales returns reserve	535	455
Other	2,242	2,045
Total accrued liabilities	$ 7,862	$ 6,516

16. Financing arrangements

Our borrowings consisted of the following (in millions):

	December 31,	
	2018	2017
6.15% notes due 2018 (6.15% 2018 Notes)	$ —	$ 500
4.375% €550 million notes due 2018 (4.375% 2018 euro Notes)	—	653
5.70% notes due 2019 (5.70% 2019 Notes)	1,000	1,000
1.90% notes due 2019 (1.90% 2019 Notes)	700	700
Floating Rate Notes due 2019	550	550
2.20% notes due 2019 (2.20% 2019 Notes)	1,400	1,400
2.125% €675 million notes due 2019 (2.125% 2019 euro Notes)	774	810
4.50% notes due 2020 (4.50% 2020 Notes)	300	300
2.125% notes due 2020 (2.125% 2020 Notes)	750	750
Floating Rate Notes due 2020	300	300
2.20% notes due 2020 (2.20% 2020 Notes)	700	700
3.45% notes due 2020 (3.45% 2020 Notes)	900	900
4.10% notes due 2021 (4.10% 2021 Notes)	1,000	1,000
1.85% notes due 2021 (1.85% 2021 Notes)	750	750
3.875% notes due 2021 (3.875% 2021 Notes)	1,750	1,750
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	1,433	1,501
2.70% notes due 2022 (2.70% 2022 Notes)	500	500
2.65% notes due 2022 (2.65% 2022 Notes)	1,500	1,500
3.625% notes due 2022 (3.625% 2022 Notes)	750	750
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	713	719
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
3.125% notes due 2025 (3.125% 2025 Notes)	1,000	1,000
2.00% €750 million notes due 2026 (2.00% 2026 euro Notes)	860	901
2.60% notes due 2026 (2.60% 2026 Notes)	1,250	1,250
5.50% £475 million notes due 2026 (5.50% 2026 pound sterling Notes)	606	642
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	893	946
6.375% notes due 2037 (6.375% 2037 Notes)	552	552
6.90% notes due 2038 (6.90% 2038 Notes)	291	291
6.40% notes due 2039 (6.40% 2039 Notes)	466	466
5.75% notes due 2040 (5.75% 2040 Notes)	412	412
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	974	974
5.65% notes due 2042 (5.65% 2042 Notes)	487	487
5.375% notes due 2043 (5.375% 2043 Notes)	261	261
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
Other notes due 2097	100	100
Unamortized discounts, premiums, issuance costs and fair value adjustments, net	(949)	(929)
Total carrying value of debt	33,929	35,342
Less current portion	(4,419)	(1,152)

Total long-term debt	$ 29,510	$ 34,190

There are no material differences between the effective interest rates and coupon rates of any of our borrowings, except for the 4.563% 2048 Notes and the 4.663% 2051 Notes, which have effective interest rates of 6.3% and 5.6%, respectively.

Under the terms of all of our outstanding notes—including debt exchange issuances, discussed below, and except our Other notes due 2097—in the event of a change-in-control triggering event we may be required to purchase all or a portion of these debt securities at prices equal to 101% of the principal amounts of the notes plus accrued and unpaid interest. In addition, all of our outstanding notes—except our floating-rate notes, 0.41% 2023 Swiss franc Bonds and Other notes due 2097—may be redeemed at any time at our option—in whole or in part—at the principal amounts of the notes being redeemed plus accrued and unpaid

interest and make-whole amounts, which are defined by the terms of the notes. Certain of the redeemable notes do not require the payment of make-whole amounts if redeemed during a specified period of time immediately prior to the maturity of the notes. Such time periods range from one to six months prior to maturity.

Debt issuances

We did not issue any debt or debt securities during the year ended December 31, 2018. We issued debt and debt securities in various offerings during the years ended December 31, 2017 and 2016 as follows:

- In 2017, we issued $4.5 billion principal amount of notes, consisting of the Floating Rate Notes due 2019, the 1.90% 2019 Notes, the Floating Rate Notes due 2020, the 2.20% 2020 Notes, the 2.65% 2022 Notes and the 3.20% 2027 Notes.

- In 2016, we issued $6.7 billion principal amount of notes, consisting of the 1.85% 2021 Notes, the 1.25% 2022 euro Notes, the 0.41% 2023 Swiss franc Bonds, the 2.25% 2023 Notes, the 2.00% 2026 euro Notes and the 2.60% 2026 Notes and $1.0 billion of the 4.40% 2045 Notes. We received a $79 million premium on the 4.40% 2045 Notes. In addition, we borrowed $605 million under a short-term floating-rate loan.

As of December 31, 2018, we have a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. During the year ended December 31, 2017, we issued and repaid an aggregate of $12.3 billion of commercial paper and had a maximum outstanding balance of $1.5 billion under our commercial paper program. During the years ended December 31, 2018 and 2016, we did not issue any commercial paper. No commercial paper was outstanding as of December 31, 2018 or 2017.

Debt repayments

In 2018, we repaid $1.1 billion of debt, including the $500 million aggregate principal amount of the 6.15% 2018 Notes and the €550 million aggregate principal amount of the 4.375% 2018 Notes revalued at $621 million upon maturity. In 2017, we repaid $4.4 billion of debt, including the $605 million short-term floating-rate loan, the $1.25 billion aggregate principal amount of the 2.125% 2017 Notes, the $600 million aggregate principal amount of the Floating Rate Notes due 2017, the $850 million aggregate principal amount of the 1.25% 2017 Notes and the $1.1 billion aggregate principal amount of the 5.85% 2017 Notes. In 2016, we repaid $3.7 billion of debt, including the remaining $1.975 billion of principal on a term loan credit facility, the $750 million aggregate principal amount of the 2.30% 2016 Notes and the $1.0 billion aggregate principal amount of the 2.50% 2016 Notes.

Debt exchange

During 2016, we completed a private offering to exchange portions of certain outstanding senior notes due 2037 through 2043 (collectively, the Old Notes), for new senior notes, consisting of principal amounts of $1.4 billion of 4.563% 2048 Notes and $3.5 billion of 4.663% 2051 Notes (collectively, the New Notes).

The New Notes bear lower fixed-coupon rates while requiring higher principal repayments on extended maturity dates compared with the Old Notes that were exchanged. There were no other significant changes to the terms between the Old Notes and the New Notes. The exchange was accounted for as a debt modification, and there were no cash payments to or cash receipts from the noteholders as a result of the exchange. Existing deferred financing costs associated with the Old Notes as well as discounts associated with the New Notes aggregating $801 million are being accreted over the term of the New Notes and recorded as Interest expense, net, in the Consolidated Statements of Income. Transaction costs of $24 million incurred for the exchange were expensed immediately in Interest and other income, net, in the Consolidated Statements of Income.

Interest rate swaps

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted fixed-rate interest coupons for certain of our debt issuances to floating London Interbank Offered Rate (LIBOR)-based coupons over the lives of the respective notes. These interest rate swap contracts qualified and are designated as fair value hedges.

The effective interest rates on notes for which we have entered into interest rate swap contracts and the related notional amounts of these contracts were as follows (dollar amounts in millions):

Notes	Effective interest rates	December 31, 2018	December 31, 2017
		Notional amounts	
2.20% 2019 Notes	LIBOR + 0.6%	$ 1,400	$ 1,400
3.45% 2020 Notes	LIBOR + 1.1%	900	900
4.10% 2021 Notes	LIBOR + 1.7%	1,000	1,000
3.875% 2021 Notes	LIBOR + 2.0%	1,750	1,750
3.625% 2022 Notes	LIBOR + 1.6%	750	750
3.625% 2024 Notes	LIBOR + 1.4%	1,400	1,400
3.125% 2025 Notes	LIBOR + 0.9%	1,000	1,000
2.600% 2026 Notes	LIBOR + 0.3%	1,250	1,250
4.663% 2051 Notes	LIBOR + 0.0%	1,500	—
Total notional amounts		$ 10,950	$ 9,450

Cross-currency swaps

In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. The terms of these contracts effectively convert the interest payments and principal repayment on our 2.125% 2019 euro Notes, 1.25% 2022 euro Notes, 0.41% 2023 Swiss franc Bonds, 2.00% 2026 euro Notes, 5.50% 2026 pound sterling Notes and 4.00% 2029 pound sterling Notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts have been designated as cash flow hedges. For information regarding the terms of these contracts, see Note 19, Derivative instruments.

Shelf registration statements and other facilities

In 2014, we entered into a $2.5 billion syndicated, unsecured, revolving credit agreement, which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $500 million with the agreement of the banks. Each bank that is a party to the agreement has an initial commitment term of five years. We extended this term by one year during 2016 and may extend the term for an additional year with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest at LIBOR plus 1% for any amounts borrowed under this facility. As of December 31, 2018 and 2017, no amounts were outstanding under this facility.

In 2017, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2020.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which was modified during 2018. The modified covenant requires that we maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest expense, each as defined and described in the amended credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2018.

Contractual maturities of debt obligations

The aggregate contractual maturities of all borrowings due subsequent to December 31, 2018, are as follows (in millions):

Maturity dates	Amounts
2019	$ 4,424
2020	2,950
2021	3,500
2022	4,183
2023	1,463
Thereafter	18,358
Total	$ 34,878

Interest costs

Interest costs are expensed as incurred except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest costs capitalized for the years ended December 31, 2018, 2017 and 2016, were not material. Interest paid, including the ongoing impact of interest rate and cross-currency swap contracts, during the years ended December 31, 2018, 2017 and 2016, was $1.5 billion, $1.3 billion and $1.2 billion, respectively.

17. Stockholders' equity

Stock repurchase program

Activity under our stock repurchase program, on a trade date basis, was as follows (in millions):

	Years ended December 31,					
	2018		2017		2016	
	Shares *	Dollars	Shares	Dollars	Shares	Dollars
First quarter	56.4	$ 10,787	3.4	$ 555	4.7	$ 690
Second quarter	18.2	3,190	6.2	1,006	3.9	591
Third quarter	8.7	1,713	4.4	769	4.4	747
Fourth quarter	11.1	2,165	4.5	796	6.7	999
Total stock repurchases	94.5	$ 17,855	18.5	$ 3,126	19.7	$ 3,027

* Total shares do not add due to rounding.

In January, April and December 2018, our Board of Directors increased the amount authorized under our stock repurchase program by $10.0 billion, $5.0 billion and $3.6 billion, respectively. Repurchase activity for the year ended December 31, 2018, included 52.1 million shares of our common stock acquired under a tender offer at an aggregate cost of $10.0 billion. As of December 31, 2018, $5.1 billion remained available under our stock repurchase program.

Dividends

Our Board of Directors declared quarterly dividends per share of $1.32, $1.15 and $1.00, which were paid in each of the four quarters of 2018, 2017, and 2016, respectively.

Historically, we have declared dividends in December of each year, which were paid in the first quarter of the following fiscal year, and in March, July and October, which were paid in the second, third and fourth quarters, respectively, of the same fiscal year. Additionally, on December 7, 2018, the Board of Directors declared a quarterly cash dividend of $1.45 per share of common stock, which will be paid on March 8, 2019, to all stockholders of record as of the close of business on February 15, 2019.

Accumulated other comprehensive income (loss)

The components of AOCI were as follows (in millions):

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2015	$ (511)	$ 297	$ (260)	$ (6)	$ (480)
Foreign currency translation adjustments	(93)	—	—	—	(93)
Unrealized (losses) gains	—	(176)	63	—	(113)
Reclassification adjustments to income	—	139	61	—	200
Other	—	—	—	1	1
Income taxes	(6)	22	(2)	—	14
Balance as of December 31, 2016	(610)	282	(138)	(5)	(471)
Foreign currency translation adjustments	77	—	—	—	77
Unrealized gains (losses)	—	192	(46)	—	146
Reclassification adjustments to income	—	(638)	41	—	(597)
Other	—	—	—	5	5
Income taxes	4	158	(1)	—	161
Balance as of December 31, 2017	(529)	(6)	(144)	—	(679)
Cumulative effect of change in accounting principle, net of tax[1]	—	—	(9)	—	(9)
Foreign currency translation adjustments	(141)	—	—	—	(141)
Unrealized gains (losses)	—	61	(556)	—	(495)
Reclassification adjustments to income	—	262	365	—	627
Other	—	—	—	(2)	(2)
Income taxes	—	(76)	6	—	(70)
Balance as of December 31, 2018	$ (670)	$ 241	$ (338)	$ (2)	$ (769)

[1] See Note 1, Summary of significant accounting policies, for additional information regarding the adoption on January 1, 2018, of the new accounting standard related to the classification and measurement of financial instruments and the related cumulative effect from the change in accounting principle.

With respect to the table above, income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for cash flow hedges were a $21 million expense and $55 million expense in 2018, a $68 million expense and $226 million benefit in 2017 and a $68 million benefit and $46 million expense in 2016, respectively. Income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for available-for-sale securities were a $9 million benefit and $3 million expense for 2018, a $9 million expense and $8 million benefit in 2017 and a $9 million benefit and $11 million expense in 2016, respectively.

Reclassifications out of AOCI and into earnings were as follows (in millions):

Components of AOCI	Years ended December 31, 2018	2017	2016	Consolidated Statements of Income locations
Cash flow hedges:				
Foreign currency contract (losses) gains	$ (21)	$ 65	$ 308	Product sales
Cross-currency swap contract (losses) gains	(241)	574	(446)	Interest and other income, net
Forward interest rate contract losses	—	(1)	(1)	Interest expense, net
	(262)	638	(139)	Income before income taxes
	55	(226)	46	Provision for income taxes
	$ (207)	$ 412	$ (93)	Net income
Available-for-sale securities:				
Net realized losses	$ (365)	$ (41)	$ (61)	Interest and other income, net
	3	(8)	11	Provision for income taxes
	$ (362)	$ (49)	$ (50)	Net income

Other

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. As of December 31, 2018 and 2017, no shares of preferred stock were issued or outstanding.

18. Fair value measurement

To estimate the fair value of our financial assets and liabilities, we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing an asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing an asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access

Level 2 — Valuations for which all significant inputs are observable either directly or indirectly—other than Level 1 inputs

Level 3 — Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

The fair values of each major class of the Company's financial assets and liabilities measured at fair value on a recurring basis were as follows (in millions):

Fair value measurement as of December 31, 2018, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Interest-bearing securities:				
U.S. Treasury notes	$ 2,663	$ —	$ —	$ 2,663
U.S. Treasury bills	8,191	—	—	8,191
Other government-related debt securities:				
U.S.	—	110	—	110
Foreign and other	—	932	—	932
Corporate debt securities:				
Financial	—	2,697	—	2,697
Industrial	—	2,504	—	2,504
Other	—	562	—	562
Residential-mortgage-backed securities	—	1,422	—	1,422
Other mortgage- and asset-backed securities	—	469	—	469
Money market mutual funds	5,659	—	—	5,659
Other short-term interest-bearing securities	—	3,515	—	3,515
Equity securities	176	—	—	176
Derivatives:				
Foreign currency contracts	—	182	—	182
Cross-currency swap contracts	—	170	—	170
Interest rate swap contracts	—	56	—	56
Total assets	$ 16,689	$ 12,619	$ —	$ 29,308
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 26	$ —	$ 26
Cross-currency swap contracts	—	401	—	401
Interest rate swap contracts	—	149	—	149
Contingent consideration obligations	—	—	72	72
Total liabilities	$ —	$ 576	$ 72	$ 648

Fair value measurement as of December 31, 2017, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Interest-bearing securities:				
U.S. Treasury notes	$ 8,242	$ —	$ —	$ 8,242
Other government-related debt securities:				
U.S.	—	223	—	223
Foreign and other	—	2,422	—	2,422
Corporate debt securities:				
Financial	—	10,072	—	10,072
Industrial	—	9,670	—	9,670
Other	—	1,390	—	1,390
Residential-mortgage-backed securities	—	2,168	—	2,168
Other mortgage- and asset-backed securities	—	2,297	—	2,297
Money market mutual funds	3,245	—	—	3,245
Other short-term interest-bearing securities	—	1,440	—	1,440
Equity securities	149	—	—	149
Derivatives:				
Foreign currency contracts	—	6	—	6
Cross-currency swap contracts	—	270	—	270
Interest rate swap contracts	—	10	—	10
Total assets	$ 11,636	$ 29,968	$ —	$ 41,604
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 204	$ —	$ 204
Cross-currency swap contracts	—	220	—	220
Interest rate swap contracts	—	61	—	61
Contingent consideration obligations	—	—	69	69
Total liabilities	$ —	$ 485	$ 69	$ 554

Interest-bearing and equity securities

The fair values of our U.S. Treasury securities, money market mutual funds and equity securities are based on quoted market prices in active markets, with no valuation adjustment.

Most of our other government-related and corporate debt securities are investment grade and have maturity dates of five years or less from the balance sheet date. Our other government-related debt securities portfolio is composed of securities with weighted-average credit ratings of A– or equivalent by Standard & Poor's Financial Services LLC (S&P), Moody's Investors Service, Inc. (Moody's) or Fitch Ratings, Inc. (Fitch); and our corporate debt securities portfolio has weighted-average credit ratings of A– or equivalent by Fitch and BBB+ or equivalent by S&P or Moody's. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry-standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

Our residential-mortgage-, other-mortgage- and asset-backed-securities portfolio is composed entirely of senior tranches with credit ratings of AAA by S&P, Moody's or Fitch. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry-standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly to estimate fair value. The inputs include reported trades of and broker-dealer

quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment or default projections based on historical data; and other observable inputs.

We value our other short-term interest-bearing securities at amortized cost, which approximates fair value given their near-term maturity dates.

Derivatives

All of our foreign currency forward and option derivative contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. These inputs, where applicable, are at commonly quoted intervals. See Note 19, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. See Note 19, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by using an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include LIBOR, swap rates and obligor credit default swap rates. See Note 19, Derivative instruments.

Contingent consideration obligations

As a result of our business acquisitions, we have incurred contingent consideration obligations, as discussed below. The contingent consideration obligations are recorded at their fair values by using probability-adjusted discounted cash flows, and we revalue these obligations each reporting period until the related contingencies have been resolved. The fair value measurements of these obligations are based on significant unobservable inputs related to licensing rights and product candidates acquired in business combinations, and are reviewed quarterly by management in our R&D and commercial sales organizations. These inputs include, as applicable, estimated probabilities and the timing of achieving specified regulatory and commercial milestones as well as estimated annual sales. Significant changes that increase or decrease the probabilities of achieving the related regulatory and commercial events or that shorten or lengthen the time required to achieve such events or that increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of the obligations, as applicable. Changes in the fair values of contingent consideration obligations are recognized in Other operating expenses in the Consolidated Statements of Income.

Changes in the carrying amounts of contingent consideration obligations were as follows (in millions):

	Years ended December 31,		
	2018	2017	2016
Beginning balance	$ 69	$ 179	$ 188
Addition from K-A acquisition	45	—	—
Net changes in valuations	(42)	(110)	(9)
Ending balance	$ 72	$ 69	$ 179

As a result of our acquisition of K-A in 2018, we are obligated to make single-digit royalty payments to Kirin contingent upon sales of brodalumab. See Note 3, Business combinations.

As a result of our acquisition of Dezima in 2015, we are obligated to pay its former shareholders up to $1.25 billion of additional consideration contingent upon achieving certain development and sales-related milestones and low single-digit royalties on net product sales above a certain threshold for AMG 899, an IPR&D asset. The fair values of the contingent consideration obligations had an aggregate value of $110 million at acquisition. During 2017, we decided to discontinue the internal development of AMG 899 and accordingly, reduced from $116 million to zero the related contingent consideration liabilities and recognized an impairment charge of $400 million on the

IPR&D asset in Other operating expenses in the Consolidated Statements of Income. The remeasurement of these liabilities and the impairment charge are included in Other items, net, in the Consolidated Statements of Cash Flows.

As a result of our acquisition of BioVex Group Inc. in 2011, we are obligated to pay its former shareholders up to $325 million upon achieving separate regulatory and sales-related milestones with regard to IMLYGIC® (talimogene laherparepvec) if certain sales thresholds are met within specified periods of time.

During the years ended December 31, 2018 and 2017, there were no transfers of assets or liabilities between fair value measurement levels. During the years ended December 31, 2018 and 2017, there were no material remeasurements to the fair values of assets and liabilities that are not measured at fair value on a recurring basis, except with respect to the IPR&D asset discussed above and in Note 14, Goodwill and other intangible assets.

Summary of the fair values of other financial instruments

Cash equivalents

The fair values of cash equivalents approximate their carrying values due to the short-term nature of such financial instruments.

Borrowings

We estimated the fair values of our borrowings by using Level 2 inputs. As of December 31, 2018 and 2017, the aggregate fair values of our borrowings were $35.0 billion and $38.6 billion, respectively, and the carrying values were $33.9 billion and $35.3 billion, respectively.

19. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we use or have used certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We do not use derivatives for speculative trading purposes.

During 2018, we adopted early a new accounting standard that amends the accounting and reporting of hedging activities. Certain required disclosures have been made on a prospective basis in accordance with the guidance of the standard. See Note 1, Summary of significant accounting policies.

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates associated primarily with our euro-denominated international product sales. Increases and decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are offset partially by corresponding increases and decreases in the cash flows from our international operating expenses resulting from these foreign currency exchange rate movements. To further reduce our exposure to foreign currency exchange rate fluctuations with regard to our international product sales, we enter into foreign currency forward and option contracts to hedge a portion of our projected international product sales primarily over a three-year time horizon, with, at any given point in time, a higher percentage of nearer-term projected product sales being hedged than in successive periods.

As of December 31, 2018, 2017 and 2016, we had foreign currency forward contracts with notional amounts of $4.5 billion, $4.6 billion and $3.4 billion, respectively, and foreign currency option contracts with notional amounts of $21 million, $74 million and $608 million, respectively. We have designated these foreign currency forward and foreign currency option contracts, which are primarily euro based, as cash flow hedges. Accordingly, we report the unrealized gains and losses on these contracts in AOCI in the Consolidated Balance Sheets, and we reclassify them to Product sales in the Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term debt denominated in foreign currencies, we enter into cross-currency swap contracts. Under the terms of such contracts, we paid euros, pounds sterling and Swiss francs and received U.S. dollars for the notional amounts at the inception of the contracts; and based on these notional amounts, we exchange interest payments at fixed rates over the lives of the contracts by paying U.S. dollars and receiving euros, pounds sterling and Swiss francs. In addition, we will pay U.S. dollars to and receive euros, pounds sterling and Swiss francs from the counterparties at the maturities of the contracts for these same notional amounts. The terms of these contracts correspond to the related hedged debt, thereby effectively converting the interest payments and principal repayment on the debt from euros, pounds sterling and Swiss francs to U.S. dollars. We have designated these cross-currency swap contracts as cash flow hedges.

Accordingly, the unrealized gains and losses on these contracts are reported in AOCI in the Consolidated Balance Sheets and

reclassified to Interest and other income, net, in the Consolidated Statements of Income in the same periods during which the hedged debt affects earnings.

The notional amounts and interest rates of our cross-currency swaps as of December 31, 2018, were as follows (notional amounts in millions):

	Foreign currency			U.S. dollars	
Hedged notes	Notional amounts		Interest rates	Notional amounts	Interest rates
2.125% 2019 euro Notes	€	675	2.1 %	$ 864	2.6 %
1.25% 2022 euro Notes	€	1,250	1.3 %	$ 1,388	3.2 %
0.41 % 2023 Swiss franc Bonds	CHF	700	0.4 %	$ 704	3.4 %
2.00% 2026 euro Notes	€	750	2.0 %	$ 833	3.9 %
5.50% 2026 pound sterling Notes	£	475	5.5 %	$ 747	6.0 %
4.00% 2029 pound sterling Notes	£	700	4.0 %	$ 1,111	4.5 %

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Consolidated Balance Sheets and are amortized into Interest expense, net, in the Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the year ended December 31, 2018, and amounts expected to be recognized during the subsequent 12 months are not material.

The unrealized gains and losses recognized in AOCI for our derivative instruments designated as cash flow hedges were as follows (in millions):

	Years ended December 31,		
Derivatives in cash flow hedging relationships	2018	2017	2016
Foreign currency contracts	$ 348	$ (402)	$ 115
Cross-currency swap contracts	(287)	581	(281)
Forward interest rate contracts	—	13	(10)
Total unrealized gains (losses)	$ 61	$ 192	$ (176)

The locations in the Consolidated Statements of Income and the gains and losses reclassified out of AOCI and into earnings for our derivative instruments designated as cash flow hedges were as follows (in millions):

		Years ended December 31,		
Derivatives in cash flow hedging relationships	Consolidated Statements of Income locations	2018	2017	2016
Foreign currency contracts	Product sales	$ (21)	$ 65	$ 308
Cross-currency swap contracts	Interest and other income, net	(241)	574	(446)
Forward interest rate contracts	Interest expense, net	—	(1)	(1)
Total realized (losses) gains		$ (262)	$ 638	$ (139)

No portions of our cash flow hedge contracts were excluded from the assessment of hedge effectiveness. As of December 31, 2018, the amount expected to be reclassified out of AOCI and into earnings during the next 12 months is $110 million of net losses on our foreign currency and cross-currency swap contracts.

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified for and were designated as fair value hedges. These interest rate swap contracts effectively convert fixed-rate coupons to floating-rate LIBOR-based coupons over the terms of the related hedge contracts. During the year ended December 31, 2018, we entered into $1.5 billion of interest rate swaps. As of December 31, 2018 and 2017, we had interest rate swap contracts with aggregate notional amounts of $10.95 billion and $9.45 billion, respectively, that hedge certain of our long-term debt issuances. See Note 16, Financing arrangements—Interest rate swaps.

For interest rate swap contracts that qualify for and are designated as fair value hedges, we recognize in Interest expense, net, in the Consolidated Statements of Income, the unrealized gain or loss on the derivative resulting from the change in fair value during the period, as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. If a hedging relationship involving an interest rate swap contract is terminated, the gain or loss realized on contract termination is recorded as an adjustment to the carrying value of the debt and amortized into Interest expense, net, over the remaining life of the previously hedged debt.

Net unrealized gains and losses on our outstanding interest rate swap contracts were as follows (in millions):

	Years ended December 31,		
Derivatives in fair value hedging relationships	**2018**	**2017**	**2016**
Net unrealized losses recognized on interest rate swap contracts	$ (42)	$ (85)	$ (34)
Net unrealized gains recognized on related hedged debt	$ 42	$ 85	$ 34

The hedged liabilities and related cumulative-basis adjustments for fair value hedges of those liabilities were recorded in the Consolidated Balance Sheets as follows (in millions):

	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
	December 31,		December 31,	
Consolidated Balance Sheets locations	**2018**	**2017**	**2018**	**2017**
Current portion of long-term debt	$ 2,396	$ 500	$ (3)	$ 23
Long-term debt	$ 9,361	$ 10,516	$ (50)	$ (11)

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(1) Current portion of long-term debt includes $1.0 billion and $500 million of carrying value with discontinued hedging relationships as of December 31, 2018 and 2017, respectively. Long-term debt includes $137 million and $1.1 billion of carrying value with discontinued hedging relationships as of December 31, 2018 and 2017, respectively.

(2) Current portion of long-term debt includes $3 million and $23 million of hedging adjustments on discontinued hedging relationships as of December 31, 2018 and 2017, respectively. Long-term debt includes $37 million and $40 million of hedging adjustments on discontinued hedging relationships as of December 31, 2018 and 2017, respectively.

The following table summarizes the amounts recorded in income and expense line items and the effects thereon from fair value and cash flow hedging, including discontinued hedging relationships (in millions):

	Year ended December 31, 2018		
	Product sales	Interest and other income, net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 22,533	$ 674	$ (1,392)
The effects of cash flow and fair value hedging:			
Losses on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ (21)		
Cross-currency swap contracts		$ (241)	
Gains (losses) on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]			$ 65
Derivatives designated as hedging instruments			$ (42)

[1] The amounts include benefits of $23 million related to the amortization of the cumulative amount of fair value hedging adjustments included in the carrying amount of the hedged debt for discontinued hedging relationships for the year ended December 31, 2018.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. These exposures are hedged on a month-to-month basis. As of December 31, 2018, 2017 and 2016, the total notional amounts of these foreign currency forward contracts were $737 million, $757 million and $666 million, respectively. The fair values of these derivatives as of December 31, 2018 and 2017, were not material.

The location in the Consolidated Statements of Income and the amounts of gains (losses) recognized in earnings for our derivative instruments not designated as hedging instruments were as follows (in millions):

		Years ended December 31,		
Derivatives not designated as hedging instruments	Consolidated Statements of Income location	2018	2017	2016
Foreign currency contracts	Interest and other income, net	$ 34	$ 24	$ (56)

The fair values of derivatives included in the Consolidated Balance Sheets were as follows (in millions):

	Derivative assets		Derivative liabilities	
December 31, 2018	**Consolidated Balance Sheets locations**	**Fair values**	**Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 181	Accrued liabilities/ Other noncurrent liabilities	$ 26
Cross-currency swap contracts	Other current assets/ Other assets	170	Accrued liabilities/ Other noncurrent liabilities	401
Interest rate swap contracts	Other current assets/ Other assets	56	Accrued liabilities/ Other noncurrent liabilities	149
Total derivatives designated as hedging instruments		407		576
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	1	Accrued liabilities	—
Total derivatives not designated as hedging instruments		1		—
Total derivatives		$ 408		$ 576

	Derivative assets		Derivative liabilities	
December 31, 2017	**Consolidated Balance Sheets locations**	**Fair values**	**Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 6	Accrued liabilities/ Other noncurrent liabilities	$ 204
Cross-currency swap contracts	Other current assets/ Other assets	270	Accrued liabilities/ Other noncurrent liabilities	220
Interest rate swap contracts	Other current assets/ Other assets	10	Accrued liabilities/ Other noncurrent liabilities	61
Total derivatives designated as hedging instruments		$ 286		$ 485

Our derivative contracts that were in liability positions as of December 31, 2018, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our, or the surviving entity's, creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right but not the obligation to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the contracts may be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

The cash flow effects of our derivative contracts are included within Net cash provided by operating activities in the Consolidated Statements of Cash Flows.

20. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See Part I, Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations*. We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote.

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Our legal proceedings involve various aspects of our business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing in which we could incur a liability, our opponents seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process, which in complex proceedings of the sort we face often extend for several years. As a result, none of the matters described in this filing in which we could incur a liability have progressed sufficiently through discovery and/or the development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. In addition, while some of the matters described in this filing do not present circumstances in which we could incur a liability (such as some matters involving our claims that others have infringed our patents and in which such others have not asserted counterclaims against us), such matters nevertheless have the potential to significantly impact our business. While it is not possible to accurately predict or determine the eventual outcomes of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain recent developments concerning our legal proceedings and other matters are discussed below:

Sensipar® (cinacalcet) Abbreviated New Drug Application (ANDA) Patent Litigation

Amgen Inc. v. Aurobindo Pharma Ltd. et al.

Beginning in September 2016, Amgen filed 14 separate lawsuits in the U.S. District Court for the District of Delaware (the Delaware District Court) for infringement of our U.S. Patent No. 9,375,405 (the ’405 Patent) against a number of manufacturers of purported generic versions of our Sensipar® product. In February 2017, the Delaware District Court consolidated these 14 lawsuits into a single case, *Amgen Inc. v. Aurobindo Pharma Ltd. et al.* The ’405 Patent is entitled “Rapid Dissolution Formulation of a Calcium Receptor-Active Compound” and expires in 2026. All defendants responding to the complaint denied infringement and sought judgment that the ’405 Patent is invalid and/or not infringed. Between September and November of 2017, Amgen filed, and the Delaware District Court signed, stipulated dismissals of the lawsuit against Micro Labs Ltd. and Micro Labs USA, Inc., and the lawsuit against Apotex Inc. and Apotex Corp. (collectively, Apotex), as well as consent judgments filed by Amgen and each of (1) Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, Sun), (2) Ajanta Pharma Limited and Ajanta Pharma USA, Inc., (3) Hetero USA Inc., Hetero Labs Ltd. and Hetero Labs Ltd. Unit V and (4) Breckenridge Pharmaceutical, Inc. (Breckenridge). Each consent judgment stipulated to an entry of judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of, or distribution into the United States of the respective defendant’s cinacalcet product during the term of the ’405 Patent unless specifically authorized pursuant to the confidential settlement agreement.

In June 2017, Amgen filed four additional lawsuits in the Delaware District Court for infringement of the ’405 Patent against additional defendants. These defendants also responded to the complaint denying infringement and seeking a declaration of noninfringement and invalidity of the ’405 Patent. One of these lawsuits was subsequently consolidated into *Amgen Inc. v. Aurobindo Pharma Ltd. et al*. and the remaining three of these lawsuits were consolidated into a separate single case, *Amgen Inc. v. Alkem et al.* (see below).

On March 5, 2018, the Delaware District Court commenced trial on the infringement claims and defenses in the *Amgen Inc. v. Aurobindo Pharma Ltd. et al.* consolidated lawsuit against the defendants that remained in the lawsuit, collectively consisting of (1) Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, Aurobindo), (2) Watson Laboratories, Inc. and Actavis Pharma, Inc. (collectively, Watson), (3) Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Co. India Private Limited, (4) Zydus

Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, Zydus) and (5) Piramal Healthcare UK Limited (Piramal).

Just prior to trial, the Delaware District Court signed consent judgments filed by Amgen and each of Cipla Limited and Cipla USA, Inc. (collectively, Cipla) and Strides Pharma Global PTE Limited and Strides Pharma, Inc. (collectively, Strides), and in

March 2018 the Delaware District Court signed a consent judgment filed by Amgen and Aurobindo. In each consent judgment, the parties stipulated to an entry of judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of, or distribution into the United States of the applicable defendant’s cinacalcet product during the term of the ’405 Patent unless specifically authorized pursuant to the applicable confidential settlement agreement. Just prior to trial, the Delaware District Court also entered orders dismissing each of Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, Dr. Reddy’s), and Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan), on stipulations between Amgen and such parties, respectively, subject to the terms of confidential settlement agreements.

On July 27, 2018, the Delaware District Court issued a trial order finding on the infringement claims and defenses in the *Amgen Inc. v. Aurobindo Pharma Ltd. et al.* consolidated lawsuit that Zydus infringes the ’405 Patent and that Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal), Piramal and Watson do not infringe the ’405 Patent. On August 24, 2018, the Delaware District Court issued an order dismissing, without prejudice, the invalidity counterclaims of Amneal, Piramal and Watson and entered judgment of noninfringement of the ’405 Patent in favor of Amneal, Piramal and Watson. On September 20, 2018, Amgen filed a notice of appeal to the Federal Circuit Court. On October 9, 2018, the Delaware District Court dismissed, without prejudice, the invalidity counterclaims of Zydus and entered judgment of infringement of the ’405 Patent by Zydus in favor of Amgen, including an order that the effective date of the U.S. Food and Drug Administration (FDA) approval of Zydus’ generic version of Sensipar® shall be no earlier than the expiry date of our ’405 Patent. On October 11, 2018, Zydus filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court) and on October 24, 2018, the Federal Circuit Court consolidated the appeals of Zydus and Amgen.

In December 2018, the FDA approved Watson’s generic version of Sensipar® and Watson’s parent company, Teva Pharmaceutical Industries Ltd. (Teva), began selling its product at-risk notwithstanding that the appeals were pending at the Federal Circuit Court. On January 2, 2019, Amgen, Watson and Teva entered into a settlement agreement in which Teva agreed to stop selling its generic product until the mid-year 2021, or earlier under certain circumstances, and to pay Amgen an undisclosed amount. On January 9, 2019, Watson and Amgen filed a motion asking the Delaware District Court to vacate its final judgment of noninfringement as to Watson and to enter a proposed consent judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the making, having made, using, selling, offering to sell, or distributing Watson’s cinacalcet product in the United States, or importing Watson’s cinacalcet product into the United States, consistent with the confidential settlement agreement. On January 11, 2019, the Federal Circuit Court stayed the pending appeal as to Watson in order for the Delaware District Court to rule on the motion of Watson and Amgen. On January 18, 2019 and January 23, 2019, respectively, Cipla and Sun filed oppositions to the motion of Watson and Amgen.

On January 8, 2019, Cipla filed a separate lawsuit in the Delaware District Court against Amgen seeking a declaration that provisions of its settlement agreement with Amgen have been triggered by Teva’s at-risk launch of Watson’s generic version of Sensipar®, giving Cipla a right to market its own generic version under its settlement agreement. Cipla’s complaint also alleges antitrust violations by Amgen. The portions of the complaint covering Cipla’s settlement agreement were filed with the court under seal and remain confidential.

Amgen Inc. v. Alkem et al.

As stated above, Amgen filed four lawsuits in June 2017 for infringement of the ’405 Patent. In December 2017, the lawsuits filed against (1) Alkem Laboratories Ltd. (Alkem), (2) Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, Lupin) and (3) Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, Macleods) were consolidated into a separate single case, *Amgen Inc. v. Alkem et al.* In each of those three lawsuits, all defendants responded to the complaint denying infringement and seeking a declaration of noninfringement and invalidity of the ’405 Patent; Macleods’ response also included a counterclaim alleging sham litigation in violation of the Sherman Antitrust Act, which Amgen has denied and which the Delaware District Court stayed pending resolution of the patent claims.

In March 2018, the Delaware District Court signed a consent judgment filed by Amgen and Macleods in which the parties stipulated to an entry of judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of, or distribution into the United States of Macleods’ cinacalcet product during the term of the ’405 Patent unless specifically authorized pursuant to the confidential settlement agreement. In April 2018, the Delaware District Court also entered orders respectively dismissing Lupin and Alkem on stipulations between the parties, subject to the terms of confidential settlement agreements.

Other Sensipar® ANDA Patent Litigation

In December 2017, Amgen filed four additional lawsuits in the Delaware District Court for infringement of the ’405 Patent against (1) Watson, (2) Teva Pharmaceuticals, USA, Inc., (3) Barr Laboratories, Inc. and (4) Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. These lawsuits were distinct from the suits consolidated into *Amgen Inc. v. Aurobindo Pharma Ltd. et al.*, and all four additional suits were subsequently dismissed by agreement between Amgen and the respective defendants.

In June 2018, Amgen filed a lawsuit in the Delaware District Court against Accord Healthcare, Inc. (Accord) and Intas Pharmaceuticals Ltd. (Intas) for infringement of the ’405 Patent. Amgen seeks an order making any FDA approval of these defendants’ generic version of Sensipar® effective no earlier than the expiration of the ’405 Patent. On September 18, 2018, Accord denied infringement of the ’405 Patent and alleged that the patent is invalid. On September 20, 2018, Intas was dismissed from the Delaware District Court lawsuit without prejudice by joint stipulation of the parties. On February 1, 2019, Accord filed a motion for summary judgment of noninfringement. Trial is scheduled to begin June 15, 2020.

On September 7, 2018, Amgen filed a lawsuit in the Delaware District Court for infringement of the ’405 Patent against Emcure Pharmaceuticals Ltd., Heritage Pharmaceuticals Inc. and Heritage Pharma Labs Inc. In December 2018, the Delaware District Court entered an order dismissing all defendants on a stipulation between the parties, subject to the terms of a confidential settlement agreement.

KYPROLIS® (carfilzomib) ANDA Patent Litigation

Beginning in October 2016, our subsidiary Onyx Therapeutics, Inc. (Onyx Therapeutics), filed four separate lawsuits in the Delaware District Court against: (1) Cipla, (2) Sagent Pharmaceuticals, Inc. (Sagent), (3) Breckenridge and (4) Fresenius Kabi, USA LLC, Fresenius Kabi USA, Inc., Fresenius Pharmaceuticals Holding, Inc. and Fresenius Kabi Oncology Limited, each for infringing U.S. Patent Nos. 7,232,818 (the ’818 Patent), 7,417,042 (the ’042 Patent), 7,491,704 (the ’704 Patent), 7,737,112 (the ’112 Patent), 8,129,346 (the ’346 Patent), 8,207,125 (the ’125 Patent), 8,207,126 (the ’126 Patent), 8,207,127 (the ’127 Patent) and 8,207,297 (the ’297 Patent). By joint stipulation of the parties, Fresenius Pharmaceuticals Holding, Inc. and Fresenius Kabi Oncology Limited were subsequently dismissed from the lawsuit against them. In October and November 2016, Onyx Therapeutics also filed four separate lawsuits in the Delaware District Court against: (1) MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (collectively, MSN), (2) Dr. Reddy’s, (3) Qilu Pharma, Inc. and Qilu Pharmaceutical Co. Ltd. (collectively, Qilu) and (4) Apotex, each for infringing the ’112 Patent; and a separate lawsuit against InnoPharma, Inc. (InnoPharma) for infringement of the ’042, ’112 and ’297 Patents. In April 2017, Onyx Therapeutics filed a separate lawsuit in the Delaware District Court against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. for infringement of the ’818, ’042, ’704, ’112, ’346, ’125, ’126, ’127 and ’297 Patents. The Delaware District Court has consolidated these ten lawsuits for purposes of discovery into a single case, *Onyx Therapeutics, Inc. v. Cipla Limited., et al*.

In August 2017, Onyx Therapeutics filed additional lawsuits in the Delaware District Court against InnoPharma for infringement of the ’818, ’704, ’346, ’125, ’126 and ’127 Patents; and against Apotex and Qilu for infringement of the ’818, ’042, ’704, ’346, ’125, ’126, ’127 and ’297 Patents. On September 14, 2017, the Delaware District Court consolidated these three additional lawsuits for purposes of discovery into the existing consolidated case.

In September 2017, by joint stipulation of the parties, Teva Pharmaceutical Industries Ltd. was dismissed from the suit against it, leaving Teva Pharmaceuticals USA, Inc., as the remaining defendant in that litigation.

In November 2017, Onyx Therapeutics filed a lawsuit in the Delaware District Court against Aurobindo Pharma USA, Inc. (Aurobindo) for infringement of the ’818, ’042, ’704, ’112, ’346, ’125, ’126, ’127 and ’297 Patents. In December 2017, Onyx Therapeutics filed additional lawsuits in the Delaware District Court against Dr. Reddy’s for infringement of the ’818, ’042, ’704, ’346, ’125, ’126, ’127 and ’297 Patents, and against MSN for infringement of the ’112 Patent. In January 2018, Onyx Therapeutics filed a lawsuit in the Delaware District Court against Apotex for infringement of the ’818, ’042, ’704, ’112, ’346, ’125, ’126, ’127 and ’297 Patents.

In February 2018, Qilu and Teva Pharmaceuticals USA, Inc. were each dismissed from the applicable lawsuits by joint stipulation of the parties. On February 7, 2018, the Delaware District Court also consolidated for purposes of discovery the lawsuit against Aurobindo into the existing consolidated case, *Onyx Therapeutics, Inc. v. Cipla Limited, et al.* On March 20, 2018, the Delaware District Court entered a stipulation between the parties providing Aurobindo a covenant not to sue on the ’818,’704,’346 and ’297 Patents.

On February 15, 2018, Onyx Therapeutics filed a lawsuit in the Delaware District Court against Breckenridge for patent infringement, and subsequently amended the complaint on March 9, 2018 to assert infringement of the ’042, ’112, ’125, ’126 and ’127 Patents. On April 20, 2018, Onyx Therapeutics filed a lawsuit in the Delaware District Court against Cipla for patent infringement of the ’042, ’112, ’125, ’126 and ’127 Patents.

The lawsuits filed between 2016-2018 are based on ANDAs that seek approval to market generic versions of KYPROLIS® before expiration of the asserted patent or patents. In each lawsuit, Onyx Therapeutics seeks an order of the Delaware District Court making any FDA approval of the respective defendant’s ANDA effective no earlier

than the expiration of the applicable patents. Responses to the complaints have been filed by all defendants alleging invalidity and, in certain instances, noninfringement of the patents.

During April 2018, the Delaware District Court entered orders on stipulations between Onyx Therapeutics and each of Apotex, Dr. Reddy's and Sagent, respectively, that each defendant infringes the '042, '112, '125, '126 and '127 Patents, and that Onyx Therapeutics will not assert patent infringement of the '818, '704, '346 and '297 Patents against certain of the respective defendants' ANDA applications and products. During May, June and July of 2018, the Delaware District Court entered orders on stipulations between Onyx Therapeutics and each of Fresenius Kabi, USA LLC and Fresenius Kabi USA, Inc. (collectively, Fresenius), Breckenridge, Aurobindo, Cipla and Innopharma, respectively, that each defendant infringes the '042, '112, '125, '126 and '127 Patents. Onyx Therapeutics had previously provided those defendants a covenant that it would not assert patent infringement of the '818,'704,'346 and '297 Patents against certain of the respective defendants' ANDA applications and products. On June 4, 2018, the Delaware District Court also entered an order on a stipulation between Onyx Therapeutics and MSN that MSN infringes the '112 Patent.

In December 2018, Apotex, Dr. Reddy's, Fresenius, InnoPharma, Sagent, Breckenridge, Aurobindo and Cipla amended their responses to the complaints to add the defense of unclean hands and to seek declarations of unenforceability of the asserted patents based on allegations of inequitable conduct. In January 2019, MSN amended its responses to the complaints to add the defense of unclean hands. Trial in the consolidated case is scheduled to commence on May 6, 2019.

On January 11, 2019, Onyx Therapeutics filed a separate lawsuit in the Delaware District Court against Breckenridge for infringing the '042, '112 and '125 Patents in connection with its ANDA that seeks approval to market generic versions of KYPROLIS® before expiration of those patents. Onyx Therapeutics seeks an order from the Delaware District Court making any FDA approval of Breckenridge's ANDA effective no earlier than the expiration of the applicable patents.

Sandoz ENBREL (etanercept) Patent Litigation

On February 26, 2016, two affiliates of Amgen Inc. (Immunex Corporation and Amgen Manufacturing, Limited (AML) (collectively, Amgen)), along with Hoffmann-La Roche Inc. (Roche), filed a lawsuit in the U.S. District Court for the District of New Jersey (the New Jersey District Court) against Sandoz Inc., Sandoz International GmbH and Sandoz GmbH (collectively, Sandoz). This lawsuit stems from Sandoz's submission of an application for FDA licensure of an etanercept product as biosimilar to Amgen's ENBREL. Amgen and Roche have asserted infringement of five patents: U.S. Patent Nos. 8,063,182 (the '182 Patent); 8,163,522 (the '522 Patent); 7,915,225; 8,119,605; and 8,722,631 (the '631 Patent). By their complaint, Amgen and Roche seek an injunction to prohibit Sandoz from commercializing its biosimilar etanercept product in the United States prior to the expiry of such patents. Responses have been filed by all Sandoz defendants denying infringement and/or asserting that the patents at issue are invalid. On August 11, 2016, and subject to the terms of a confidential stipulation, the New Jersey District Court entered a preliminary injunction prohibiting Sandoz from making, using, importing, selling or offering for sale Sandoz's etanercept product. On August 30, 2016, the FDA approved Sandoz's Erelzi™, a biosimilar to ENBREL.

On September 14, 2017, Amgen filed a motion for summary judgment that Sandoz infringed claim 1 of the '631 Patent and, on October 23, 2017, Sandoz filed its brief in opposition to the motion.

On September 10, 2018, the New Jersey District Court entered an order that the making, using, offering to sell or selling in the United States, or the importation into the United States by Sandoz of Sandoz's biosimilar etanercept product infringes the '182 Patent and the '522 Patent. The New Jersey District Court held a bench trial from September 11, 2018, to September 25, 2018, focusing on Sandoz's challenges to the validity of these patents. Closing arguments were heard on November 19, 2018, and the parties await the court's verdict.

NEUPOGEN® (filgrastim) / Neulasta® (pegfilgrastim) Patent Litigation

Adello NEUPOGEN® Patent Litigation

On March 8, 2018, Amgen Inc. and AML (collectively, Amgen) filed a lawsuit in the New Jersey District Court against Adello Biologics, LLC (Adello). This lawsuit stems from Adello's submission of an application for FDA licensure of a filgrastim product as biosimilar to Amgen's NEUPOGEN®. Amgen has asserted infringement of 17 of our patents. Amgen seeks an injunction to prohibit Adello from commercializing its biosimilar filgrastim product in the United States prior to the expiry of these patents. On May 17, 2018, Adello responded to Amgen's lawsuit for patent infringement, denying infringement and seeking judgment that the patents-in-suit are invalid and not infringed.

On October 3, 2018, Amgen filed a first amended complaint in the New Jersey District Court adding as defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc. (collectively, Amneal) and reducing the

number of patents-in-suit from 17 to 4: U.S. Patent Nos. 8,940,878 (the ’878 Patent); 8,952,138 (the ’138 Patent); 9,643,997 (the ’997 Patent); and 9,856,287 (the ’287 Patent). On October 17, 2018, Adello responded to the first amended complaint, seeking judgment that our patents-in-suit are not infringed by Adello’s biosimilar filgrastim product and that our patents are invalid. On December 5, 2018, Amneal filed a motion to dismiss the claims against it for failure to state a claim and for lack of subject-matter jurisdiction.

Apotex NEUPOGEN® / Neulasta® Patent Litigation

On August 7, 2018, Amgen filed a lawsuit in the U.S. District Court for the Southern District of Florida against Apotex for infringement of the ’287 Patent in accordance with the patent provisions of the Biologics Price Competition and Innovation Act (BPCIA). This lawsuit stems from Apotex’s submissions of applications for FDA licensure of a pegfilgrastim product as biosimilar to Amgen’s Neulasta® and a filgrastim product as biosimilar to Amgen’s NEUPOGEN®. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Apotex from infringing the ’287 Patent. On December 10, 2018, Apotex filed a motion to dismiss the complaint for failure to state a claim. A hearing on the motion to dismiss is scheduled for March 15, 2019.

On October 1, 2018, Apotex and Adello Biologics, LLC filed a petition in the U.S. Patent and Trademark Office requesting that the Patent Trial and Appeal Board (PTAB) institute post grant review proceedings on the ’287 Patent. On January 23, 2019, Amgen filed a patent owner’s preliminary response.

On February 17, 2017, the PTAB of the U.S. Patent and Trademark Office granted Apotex’s petition to institute an *inter partes* review (IPR) of the ’138 Patent, challenging claims of the ’138 Patent as unpatentable. On May 22, 2017, Amgen filed its response and oral argument was held before the PTAB on December 13, 2017. The PTAB issued a final decision on the IPR of the ’138 Patent holding all but one claim of the ’138 Patent as unpatentable. On March 16, 2018, Apotex filed a request for rehearing on the PTAB’s finding that this one claim is patentable.

Coherus Neulasta® Patent Litigation

On May 10, 2017, Amgen filed a lawsuit in the Delaware District Court against Coherus BioSciences, Inc. (Coherus) for infringement of our U.S. Patent No. 8,273,707 (the ’707 Patent). This lawsuit stems from Coherus’ submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen’s Neulasta® under the BPCIA. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Coherus from infringing the ’707 Patent. On March 26, 2018, the Delaware District Court granted Coherus’ motion to dismiss Amgen’s complaint for failure to state a claim and final judgment was entered dismissing Amgen’s complaint on April 18, 2018. On May 17, 2018, Amgen appealed the judgment to the Federal Circuit Court. On November 2, 2018, the FDA approved Coherus’ UDENYCA™, a biosimilar to Neulasta®, which was subsequently launched in January 2019.

We are also engaged in a separate lawsuit in which we have alleged that Coherus and others misappropriated our confidential information and trade secrets through hiring of former Amgen employees and that they have used such information to develop and market UDENYCA™. Trial is scheduled to begin on April 22, 2019.

Mylan Neulasta® Patent Litigation

On September 22, 2017, Amgen Inc. and AML (collectively, Amgen) filed a lawsuit in the District Court for the Western District of Pennsylvania (the Pennsylvania Western District Court) against Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. (collectively, Mylan) for infringement of our ’707 Patent and the ’997 Patent. This lawsuit stems from Mylan’s submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen’s Neulasta® under the BPCIA. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Mylan from infringing the ’707 and ’997 Patents. On November 22, 2017, Mylan answered the complaint, denying patent infringement and alleging that the patents are invalid. On April 6, 2018, Mylan filed a motion for judgment on the pleadings of noninfringement of our ’707 Patent, which was denied by the court without prejudice on November 15, 2018. On June 4, 2018, the FDA approved Mylan’s Fulphila®, a biosimilar to Neulasta®, which was subsequently launched in July 2018. On November 20, 2018, the Pennsylvania Western District Court issued a claim construction opinion and order. On January 23 and 30, 2019, Mylan filed a renewed motion for judgment on the pleadings of noninfringement of the ’707 Patent and a motion for summary judgment of noninfringement of the ’997 Patent, respectively.

Pfizer NEUPOGEN® Patent Litigation

On July 18, 2018, Amgen Inc. and AML (collectively, Amgen) filed a lawsuit in the Delaware District Court against Pfizer Inc. and Hospira Inc. (collectively, Pfizer). This lawsuit stems from Pfizer’s submission of an application for FDA licensure of a filgrastim product as biosimilar to Amgen’s NEUPOGEN®. Amgen has asserted infringement of the ’997 Patent and seeks, among other remedies, injunctive relief to prohibit Pfizer from infringing the ’997 Patent. On July 20, 2018, the FDA approved Pfizer’s NIVESTYM™, a biosimilar to NEUPOGEN®, which was subsequently launched in October 2018.

On August 9, 2018, Pfizer answered the complaint and counterclaimed seeking a declaration that Pfizer does not infringe Amgen's '997 Patent and that the patent is invalid. Trial is scheduled to commence on June 15, 2020.

Sandoz NEUPOGEN® Patent Litigation

On October 24, 2014, Amgen Inc. and AML (collectively, Amgen) filed a lawsuit in the U.S. District Court for the Northern District of California (the California Northern District Court) against Sandoz Inc., Sandoz International GmbH and Sandoz GmbH

(collectively, Sandoz) for infringement of our U.S. Patent No. 6,162,427 (the '427 Patent) and various state law claims. The lawsuit stems from Sandoz filing an application for FDA licensure of a filgrastim product as biosimilar to NEUPOGEN® under the BPCIA, while having deliberately failed to comply with the BPCIA's disclosure requirement to Amgen as the reference product sponsor. By its complaint, Amgen seeks, among other remedies, an injunction to cease Sandoz's unauthorized reliance on Amgen's Biologics License Application (BLA) for filgrastim and an injunction to prevent infringement of the '427 Patent.

On March 19, 2015, the California Northern District Court issued an order dismissing with prejudice Amgen's state law claims and entered judgment in favor of Sandoz Inc. on its cross-motion for partial judgment on the pleadings. The order also denied Amgen's motion for a preliminary injunction, as well as Amgen's motion for partial judgment on the pleadings. On a joint motion of the parties, on March 25, 2015, the California Northern District Court entered final judgment on the claims and counterclaims decided by the court's March 19 order. The remaining patent infringement claim, counterclaim and defenses were stayed by the court pending appeal. On March 25, 2015, Amgen appealed both the judgment in favor of Sandoz Inc. and the denial of Amgen's motion for preliminary injunction to the Federal Circuit Court. On May 5, 2015, the Federal Circuit Court entered an injunction prohibiting Sandoz Inc. from marketing, selling, offering for sale, or importing into the United States Sandoz's FDA-approved Zarxio® biosimilar product until the Federal Circuit Court resolved the appeal.

On July 21, 2015, the Federal Circuit Court affirmed the California Northern District Court's dismissal of Amgen's state law claims concluding that the only remedies available for a biosimilar applicant's failure to provide its BLA by the statutory deadline is to bring a patent infringement claim and seek those patent remedies provided by the statute. The Federal Circuit Court also concluded that a biosimilar applicant must give 180-day advance notice of first commercial marketing after the FDA has licensed the biosimilar product. Accordingly, the Federal Circuit Court entered an order that its previously entered injunction be extended through September 2, 2015 (180 days from Sandoz Inc.'s notice given after FDA approval).

In 2016, Sandoz filed a petition for certiorari with the U.S. Supreme Court and Amgen filed a conditional cross-petition for certiorari. Both petitions were granted and on June 12, 2017, the U.S. Supreme Court reversed the Federal Circuit Court ruling that a biosimilar applicant must wait to give the 180-day advance notice of first commercial marketing until after the FDA has licensed the biosimilar product, holding that such notice can be given either before or after the FDA approval. The U.S. Supreme Court also vacated the Federal Circuit Court's decision that the only remedy available when a biosimilar applicant refuses to provide its BLA is to bring a patent infringement claim. The U.S. Supreme Court agreed with the Federal Circuit Court that there is no remedy under federal law for failing to make the disclosure but remanded the case to the Federal Circuit Court to determine whether California law would treat noncompliance with such requirement as unlawful and, if so, to determine whether the BPCIA pre-empts any additional remedy available under state law and whether Sandoz forfeited any pre-emption defense. On December 14, 2017, the Federal Circuit Court affirmed the California Northern District Court's dismissal of Amgen's state law claims, holding that the BPCIA pre-empts state law remedies for a biosimilar applicant's failure to comply with the BPCIA's disclosure requirement.

Following the California Northern District Court's September 8, 2015 lift of the stay of the case, the parties continued to litigate the remaining patent infringement claim, counterclaim and defenses. On October 15, 2015, Amgen filed a first supplemental and amended complaint adding to the lawsuit Sandoz's infringement of the '878 Patent, which covers methods of purifying proteins. On September 13, 2017, by joint stipulation of the parties, the California Northern District Court dismissed from the case the parties' respective claims and counterclaims related to the '427 Patent. On October 25, 2017, Sandoz filed motions for summary judgment of noninfringement of the '878 Patent and for summary judgment regarding damages. On December 19, 2017, the California Northern District Court granted Sandoz's summary judgment of noninfringement. Sandoz's motion for summary judgment regarding damages was denied as moot. On January 8, 2018, the California Northern District Court entered judgment of noninfringement of the '878 and '427 Patents and dismissed without prejudice Sandoz's counterclaims of invalidity of the '878 and '427 Patents. On February 5, 2018, Amgen appealed the judgment to the Federal Circuit Court. A hearing on the appeal has been scheduled for March 4, 2019.

Sandoz Neulasta® Patent Litigation

On May 12, 2016, Amgen filed a lawsuit in the California Northern District Court against Sandoz and Lek Pharmaceuticals d.d. for infringement of the '878 Patent and U.S. Patent No. 5,824,784 (the '784 Patent) in accordance with the patent provisions of the BPCIA. The lawsuit stems from Sandoz filing an application for FDA licensure of a pegfilgrastim product as biosimilar to Neulasta®. On June 23, 2016, Sandoz responded to the complaint, denying infringement and seeking judgment that the patents-in-suit are invalid and/or not infringed. On December 7, 2016, by joint stipulation of the parties, the California Northern District Court dismissed from the case

all claims and counterclaims related to the ’784 Patent. On October 25, 2017, Sandoz filed motions for summary judgment of noninfringement of the ’878 Patent and for summary judgment regarding damages. On December 19, 2017, the California Northern District Court granted Sandoz’s summary judgment of noninfringement of the ’878 Patent. Sandoz’s motion for summary judgment regarding damages was denied as moot. On January 8, 2018, the California Northern District Court entered judgment of noninfringement of the ’878 Patent and dismissed without prejudice Sandoz’s counterclaims of invalidity of the ’878 Patent. On February 5, 2018, Amgen appealed the judgment to the Federal Circuit Court. A hearing on the appeal has been scheduled for March 4, 2019.

PCSK9 Antibody Patent Litigation

U.S. Patent Litigation-Sanofi/Regeneron

On October 17, 2014, Amgen initiated a series of lawsuits in the Delaware District Court against Sanofi, Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc., and Regeneron Pharmaceuticals, Inc. (Regeneron) for patent infringement. On December 15, 2014, these lawsuits were consolidated by the Delaware District Court into a single case against Sanofi, Sanofi-Aventis U.S. LLC and Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc. (collectively, Sanofi) and Regeneron, addressing seven of our patents: U.S. Patent Nos. 8,563,698; 8,829,165 (the '165 Patent); 8,859,741 (the '741 Patent); 8,871,913; 8,871,914; 8,883,983; and 8,889,834. These patents describe and claim monoclonal antibodies to proprotein convertase subtilisin/kexin type 9 (PCSK9). By its complaints, Amgen seeks an injunction to prevent the infringing manufacture, use and sale of Sanofi and Regeneron's alirocumab, a monoclonal antibody targeting PCSK9. On January 29, 2016, the Delaware District Court granted Amgen's motion to amend the complaint to add AML and Amgen USA Inc. as plaintiffs and to add the allegation that defendants' infringement of Amgen's patents is willful.

On February 22, 2016, the Delaware District Court entered a stipulated order finding alirocumab and the drug product containing it, PRALUENT®, infringe certain of Amgen's patents, including claims 2, 7, 9, 15, 19 and 29 of the '165 Patent and claim 7 of the '741 Patent. On March 18, 2016, the Delaware District Court entered judgment in favor of Amgen following a five-day jury trial and a unanimous jury verdict that these patent claims from the '165 Patent and the '741 Patent are all valid. On January 3, 2017, the Delaware District Court denied Sanofi and Regeneron's post-trial motions seeking a new trial and for judgment as a matter of law, and on January 5, 2017, granted Amgen's motion for a permanent injunction prohibiting the infringing manufacture, use, sale, offer for sale or import of alirocumab in the United States.

On January 12, 2017, Sanofi and Regeneron filed an appeal of the judgment and the permanent injunction to the Federal Circuit Court. On February 8, 2017, following a motion by Sanofi and Regeneron, the Federal Circuit Court entered a stay of the permanent injunction during the pendency of the appeal. On October 5, 2017, the Federal Circuit Court reversed in part the judgment of the Delaware District Court and remanded for a new trial two of Sanofi and Regeneron's patent validity defenses (failure to meet the law's requirements for patentability of written description and enablement of the claimed inventions), and affirmed the Delaware District Court's judgment of infringement of claims 2, 7, 9, 15, 19 and 29 of the '165 Patent and claim 7 of the '741 Patent and patent validity on Sanofi and Regeneron's third patent validity defense (finding that the claimed inventions were not obvious to a person of ordinary skill in the field of the patents). The Federal Circuit Court also vacated and remanded for further consideration by the Delaware District Court the permanent injunction. On July 23, 2018, Amgen filed a petition for certiorari with the U.S. Supreme Court seeking review of the Federal Circuit Court's conclusion that the judgment affirming the validity of Amgen's patents was based, in part, on an erroneous application of the law of written description. On January 7, 2019, the Supreme Court denied Amgen's petition for certiorari.

On remand from the appellate court, the Delaware District Court scheduled a new trial to begin on February 19, 2019 on Sanofi and Regeneron's challenges to the validity of our patents based on lack of written description and enablement of the claimed inventions. Consideration of damages and injunctive relief will follow, as appropriate. The court also entered judgment on the pleadings for Sanofi and Regeneron on Amgen's claim of willful infringement.

Patent Disputes in the International Region

On February 24, 2016, the European Patent Office (EPO) granted European Patent No. 2,215,124 (EP 2,215,124) to Amgen. This patent describes and claims monoclonal antibodies to PCSK9 and methods of treatment. On February 24, 2016, Sanofi filed an opposition to the patent in the EPO seeking to invalidate it. In November 2016, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A. and Sanofi Winthrop Industrie S.A. filed a joint opposition against Amgen's patent, and each of Eli Lilly and Company, Regeneron and Strawman Ltd. also filed oppositions to Amgen's patent. Following a three-day hearing, on November 30, 2018, the EPO confirmed the validity of Amgen's EP 2,215,124.

We are also involved in and expect future involvement in additional disputes regarding our PCSK9 patents in other jurisdictions and regions, including matters filed against us and that we have filed in the United Kingdom, Germany, France and Japan.

Hospira EPOGEN® (epoetin alfa) Patent Litigation

On September 18, 2015, Amgen filed a lawsuit in the Delaware District Court against Hospira, Inc. (Hospira), a subsidiary of Pfizer, for infringement of Amgen's U.S. Patent Nos. 5,856,298 (the '298 Patent) and 5,756,349 (the

’349 Patent) in accordance with the patent provisions of the BPCIA and for a declaration that Hospira has failed to comply with certain requirements of the BPCIA. This lawsuit stems from the submission by Hospira under the BPCIA of an application for FDA licensure of an epoetin product as biosimilar to Amgen’s EPOGEN®. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Hospira from using or selling infringing cells and/or product manufactured during the ’298 or the ’349 Patent terms and enjoining

Hospira from commencing commercial marketing of any biosimilar epoetin product until a date that is at least 180 days after Hospira provides legally effective notice to Amgen.

On August 19, 2016, Hospira responded to the complaint denying patent infringement and any violation of the BPCIA and seeking judgment that the patents-in-suit are invalid and not infringed by Hospira. On January 23, 2017, the Delaware District Court entered an order construing the claims of the ’349 and ’298 Patents and holding that two claims of the ’298 Patent are invalid for failure to properly narrow the claim on which they depend.

On September 22, 2017, after a five-day trial, the jury returned a verdict finding the ’298 Patent valid and infringed by Hospira and the ’349 Patent not infringed. The jury awarded Amgen $70 million in damages for Hospira’s infringement. On October 23, 2017, Hospira moved for judgment as a matter of law of noninfringement and invalidity of the ’298 Patent or, in the alternative, for reduction of the damage award or a new trial on the ’298 Patent.

On May 15, 2018, the FDA approved Hospira’s RETACRIT®, a biosimilar to EPOGEN®, which was subsequently launched on November 14, 2018.

On August 27, 2018, the Delaware District Court denied Hospira’s October 23, 2017, motion and entered final judgment on September 11, 2018. On October 3, 2018, Hospira filed a notice of appeal to the Federal Circuit Court and on October 15, 2018, Amgen filed a notice of cross-appeal.

Litigation relating to our Biosimilar Products

MVASI™ (bevacizumab-awwb) Patent Litigation

On October 6 and October 18, 2017, Genentech, Inc. (Genentech) and City of Hope filed separate lawsuits in the Delaware District Court respectively alleging Amgen’s infringement of (i) 24 of the 27 patents listed by Genentech in the BPCIA exchange and (ii) 25 of the same 27 patents, in each case by Amgen’s submission for FDA licensure of MVASI™ as biosimilar to Genentech’s Avastin® (bevacizumab), and for non-compliance with certain provisions of the BPCIA. On December 6, 2017, Genentech and City of Hope amended their complaints to allege that Amgen will also infringe newly issued U.S. Patent No. 9,795,672. On April 17, 2018, the Delaware District Court granted Amgen’s motion to dismiss certain claims by Genentech and City of Hope that Amgen had not complied with the BPCIA.

Amgen responded to the complaints on May 1 and June 5, 2018, respectively, denying patent infringement and any violation of the BPCIA and seeking judgment that the patents-in-suit are invalid, unenforceable and/or not infringed by Amgen. On May 22 and June 19, 2018, respectively, Genentech and City of Hope moved to dismiss from each case all of Amgen’s counterclaims and certain of Amgen’s defenses.

On August 31, 2018, in accordance with the scheduling order issued by the Delaware District Court, Genentech and City of Hope reduced the number of asserted patents in each lawsuit to 8, asserting the same patents in each case. On October 22, 2018, the two cases were consolidated by the court. Trial is scheduled to begin on July 13, 2020.

KANJINTI™ (trastuzumab) Patent Litigation

On June 21, 2018, Genentech and City of Hope filed a lawsuit in the Delaware District Court alleging Amgen’s infringement of 37 patents by Amgen’s submission of an application for FDA licensure of KANJINTI™, Amgen’s biosimilar version of Genentech’s Herceptin® (trastuzumab). On July 19, 2018, Genentech, City of Hope and Amgen filed a joint stipulation to dismiss certain of the patents from the lawsuit and Genentech and City of Hope filed an amended complaint narrowing its allegations of infringement to 18 of the 37 patents. Among other remedies, Genentech and City of Hope seek injunctive relief prohibiting patent infringement.

On August 23, 2018, Genentech and City of Hope moved to dismiss Amgen’s unenforceability counterclaims and affirmative defense. On November 7, 2018, in accordance with the scheduling order issued by the Delaware District Court, Genentech and City of Hope reduced the number of asserted patents from 18 to 10. On January 17, 2019, Genentech and the City of Hope filed a second amended complaint that removed one of the remaining 10 asserted patents and added a different patent. Trial is scheduled to begin on or after December 9, 2019.

AMJEVITA™ (adalimumab-atto) / AMGEVITA™ Patent Litigation

On January 24, 2019, Coherus filed a lawsuit in the Delaware District Court that the formulation of AMJEVITA™ infringes three patents: U.S. Patent Nos. 10,155,039; 10,159,732; and 10,159,733. By its complaint, Coherus seeks, among other remedies, injunctive relief prohibiting patent infringement.

Amgen has also been sued in a number of European countries by Fresenius Kabi Deutschland GmbH (Fresenius), alleging that AMGEVITA™ infringes various patents of Fresenius and seeking, among other remedies, injunctive relief prohibiting patent infringement.

U.S. Attorney's Office for the District of Massachusetts-Patient Assistance Investigation

Amgen, together with other companies in our industry, has received inquiries from the U.S. Attorney's Office for the District of Massachusetts relating to support of charitable 501(c)(3) organizations that provide financial assistance to Medicare patients. Amgen is cooperating with this ongoing inquiry.

Commitments

Lease commitments

We lease certain facilities and equipment related primarily to administrative, R&D, sales and marketing activities under noncancelable operating leases that expire through 2029. The following table summarizes the minimum future rental commitments under noncancelable operating leases as of December 31, 2018 (in millions):

	Amounts
2019	$ 164
2020	126
2021	113
2022	64
2023	56
Thereafter	46
Total minimum operating lease commitments	$ 569

Included in the table above are future rental commitments for abandoned leases in the amount of $222 million. There were no material charges for lease abandonments related to the restructuring plan that commenced in 2014. See Note 2, Restructuring. We expect to receive total future rental income of $203 million relating to noncancelable subleases of abandoned facilities. Rental expenses on operating leases for the years ended December 31, 2018, 2017 and 2016, were $166 million, $159 million and $134 million, respectively.

U.S. repatriation tax commitments

Under the 2017 Tax Act, we elected to pay the repatriation tax related primarily to our prior indefinitely invested earnings of our foreign operations in eight annual installments. See Note 7, Income taxes. The following table summarizes the remaining scheduled repatriation tax payments as of December 31, 2018 (in millions):

	Amounts
2019	$ 586
2020	586
2021	586
2022	586
2023	1,099
Thereafter	3,296
Total remaining U.S. repatriation tax commitments	$ 6,739

21. Major customers

In the United States, we sell primarily to pharmaceutical wholesale distributors that we utilize as the principal means of distributing our products to healthcare providers. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

We had product sales to three customers, each of them accounting for more than 10% of total revenues for each of the years ended December 31, 2018, 2017 and 2016. For the year ended December 31, 2018, on a combined basis, these customers accounted for 84% and 98% of total gross revenues and U.S. gross product sales, respectively, as shown in the following table. Certain information with respect to these customers was as follows (dollar amounts in millions):

	Years ended December 31,		
	2018	2017	2016
AmerisourceBergen Corporation:			
Gross product sales	$ 12,091	$ 10,742	$ 10,100
% of total gross revenues	33 %	31 %	31 %
% of U.S. gross product sales	39 %	37 %	38 %
McKesson Corporation:			
Gross product sales	$ 11,434	$ 10,625	$ 9,710
% of total gross revenues	31 %	30 %	30 %
% of U.S. gross product sales	35 %	35 %	34 %
Cardinal Health, Inc.:			
Gross product sales	$ 7,475	$ 7,049	$ 6,520
% of total gross revenues	20 %	20 %	20 %
% of U.S. gross product sales	24 %	24 %	24 %

As of December 31, 2018 and 2017, amounts due from these three customers each exceeded 10% of gross trade receivables and accounted for 76% and 75%, respectively, of net trade receivables on a combined basis. As of December 31, 2018 and 2017, 23% and 25%, respectively, of trade receivables, net, were due from customers located outside the United States—primarily in Europe. Our total allowance for doubtful accounts as of December 31, 2018 and 2017 was not material.

22. Quarterly financial data (unaudited)

The following tables summarize the Company's unaudited financial data on a quarterly basis. The sum of the quarterly earnings (loss) per-share amounts may not equal the amount reported for the full year because per-share amounts are computed independently for each quarter and for the full year based on respective weighted-average shares outstanding and dilutive securities.

Quarterly financial data is summarized as follows (in millions, except per-share data):

	2018 Quarters ended			
	December 31	September 30	June 30	March 31
Product sales	$ 6,001	$ 5,510	$ 5,679	$ 5,343
Gross profit from product sales	$ 4,905	$ 4,473	$ 4,655	$ 4,399
Net income	$ 1,928	$ 1,859	$ 2,296	$ 2,311
Earnings per share:				
Basic	$ 3.04	$ 2.88	$ 3.50	$ 3.27
Diluted	$ 3.01	$ 2.86	$ 3.48	$ 3.25

	2017 Quarters ended			
	December 31	September 30	June 30	March 31
Product sales	$ 5,569	$ 5,453	$ 5,574	$ 5,199
Gross profit from product sales	$ 4,510	$ 4,463	$ 4,550	$ 4,203
Net (loss) income	$ (4,264)	$ 2,021	$ 2,151	$ 2,071
(Loss) earnings per share:				
Basic	$ (5.89)	$ 2.78	$ 2.93	$ 2.81
Diluted[1]	$ (5.89)	$ 2.76	$ 2.91	$ 2.79

(1) During periods of net loss, diluted loss per share is equal to basic loss per share because the antidilutive effect of potential common shares is disregarded.

SCHEDULE II

AMGEN INC.

VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2018, 2017 and 2016

(In millions)

Allowance for doubtful accounts	Balance at beginning of period	Additions charged to costs and expenses	Other additions	Deductions	Balance at end of period
Year ended December 31, 2018	$ 51	$ 1	$ —	$ 4	$ 48
Year ended December 31, 2017	$ 51	$ 4	$ —	$ 4	$ 51
Year ended December 31, 2016	$ 55	$ 11	$ —	$ 15	$ 51

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2017

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**95-3540776**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive, Thousand Oaks, California	**91320-1799**
(Address of principal executive offices)	(Zip Code)

(805) 447-1000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common stock, $0.0001 par value	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒	Accelerated filer ☐	Non-accelerated filer ☐	Smaller reporting company ☐
		(Do not check if a smaller reporting company)	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $125,649,811,435 as of June 30, 2017.[(A)]

(A) Excludes 1,188,740 shares of common stock held by directors and executive officers, and any stockholders whose ownership exceeds ten percent of the shares outstanding, at June 30, 2017. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

720,562,246

(Number of shares of common stock outstanding as of February 9, 2018)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2018 Annual Meeting of stockholders to be held May 22, 2018, are incorporated by reference into Part III of this annual report.

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PART I

Item 1. BUSINESS

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Our strategy is to develop innovative medicines in six focused therapeutic areas that meet important unmet medical needs in addressing serious illness. We have a presence in approximately 100 countries worldwide with a primary focus in: oncology/hematology, cardiovascular disease, inflammation, bone health, nephrology and neuroscience.

Amgen was incorporated in California in 1980 and became a Delaware corporation in 1987. Amgen operates in one business segment: human therapeutics.

Significant Developments

Following is a summary of significant developments affecting our business that have occurred and that we have reported since the filing of our Annual Report on Form 10-K for the year ended December 31, 2016, and in early 2018.

Products/Pipeline

Bone health

Prolia® (denosumab)

- In October 2017, we announced that the U.S. Food and Drug Administration (FDA) accepted for review the supplemental Biologics License Application (sBLA) for Prolia® for the treatment of patients with glucocorticoid-induced osteoporosis. The sBLA is based on a phase 3 study evaluating the safety and efficacy of Prolia® compared with risedronate in patients receiving glucocorticoid treatment. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of May 28, 2018.

XGEVA® (denosumab)

- In April 2017, we announced the submission of an application for a variation to the marketing authorization to the European Medicines Agency (EMA) for XGEVA®. The submission to the regulatory authority seeks to expand the currently approved XGEVA® indication for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors to include patients with multiple myeloma.

- In January 2018, we announced that the FDA approved the sBLA for XGEVA® to expand the currently approved indication for the prevention of SREs in patients with bone metastases from solid tumors to include patients with multiple myeloma.

- In February 2018, we announced that a phase 3 study of XGEVA® for a potential new indication as adjuvant treatment for women with high-risk, early stage breast cancer receiving standard of care neoadjuvant or adjuvant cancer therapy did not meet its primary endpoint of bone metastasis-free survival.

*EVENITY™ (romosozumab)**

- In May 2017, we and UCB, our global collaboration partner in the development of EVENITY™, announced that the EVENITY™ ARCH (Active-contRolled FraCture Study in Postmenopausal Women with Osteoporosis at High Risk of Fracture) study met both primary endpoints and the key secondary

endpoint. An imbalance in positively adjudicated cardiovascular serious adverse events was observed in the study as a new safety signal.

- In July 2017, we and UCB announced that the FDA issued a Complete Response Letter for the Biologics License Application (BLA) for EVENITY™ as a treatment for postmenopausal women with osteoporosis. We intend to provide a resubmission, which will include data from the phase 3 ARCH study and select data from the phase 3 BRIDGE (PlaceBo-contRolled Study EvaluatIng the Efficacy anD Safety of Romosozumab in TreatinG mEn with Osteoporosis) study evaluating EVENITY™ in men with osteoporosis, in addition to the phase 3 FRAME (FRActure study in postmenopausal

woMen with ostEoporosis) study. We are currently evaluating all EVENITY™ data and will be working in close collaboration with the FDA.

- In January 2018, we and UCB announced that the EMA accepted the Marketing Authorization Application (MAA) for EVENITY™ for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture.

Cardiovascular

Repatha® (evolocumab)

- In February 2017, we announced that the European Commission (EC) adopted a decision to change the Repatha® marketing authorization, approving a new single-dose, monthly delivery option. The new automated mini-doser with a pre-filled cartridge is a hands-free device that provides 420 mg of Repatha® in a single injection per administration.

- In March 2017, we announced that the phase 3 study evaluating Repatha® in patients who were receiving apheresis to reduce low-density lipoprotein cholesterol (LDL-C) met its primary endpoint.

- In June 2017, we announced the submission of an application for a variation to the marketing authorization to the EMA for Repatha®. The regulatory submission is based on the Repatha® cardiovascular outcomes study, FOURIER (Further Cardiovascular OUtcomes Research with Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibition in Subjects with Elevated Risk).

- In October 2017, the U.S. Court of Appeals for the Federal Circuit issued a ruling that reversed in part the decision of the U.S. District Court for the District of Delaware that had prohibited Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc., and Regeneron Pharmaceuticals, Inc. from infringing two patents that we hold for Repatha® by manufacturing, using, selling, offering for sale or importing alirocumab in the United States. See Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

- In October 2017, we announced that a phase 3 study of Repatha® on top of maximally tolerated statin therapy in type 2 diabetic patients with hypercholesterolemia met its co-primary endpoints of the percent reduction from baseline in LDL-C at week 12 and the mean percent reduction from baseline in LDL-C at weeks 10 and 12. No new safety findings were identified.

- In December 2017, we announced that following priority review of our sBLA, the FDA approved Repatha® as the first PCSK9 inhibitor to prevent heart attacks, strokes and coronary revascularizations in adults with established cardiovascular disease based on data from the Repatha® cardiovascular outcomes study. The FDA also approved Repatha® to be used as an adjunct to diet, alone or in combination with other lipid-lowering therapies, such as statins, for the treatment of adults with primary hyperlipidemia to lower LDL-C. The new label also included data from the Repatha® cognitive function study showing Repatha® was non-inferior to placebo on selected cognitive function domains as assessed with the use of neuropsychological function tests over a median follow-up of 19 months.

Neuroscience

*Aimovig™ (erenumab)**

- In April 2017, we announced an expanded collaboration with Novartis AG (Novartis) for Aimovig™, which is being investigated for the prevention of migraine. As part of the expanded collaboration, Amgen and Novartis agreed to combine capabilities to co-commercialize Aimovig™ in the United States.

- In July 2017, we announced that the FDA accepted for review the BLA for Aimovig™ for the prevention of migraine in patients experiencing four or more migraine days per month. The FDA has set a PDUFA target action date of May 17, 2018.

- In January 2018, a phase 3b study met its primary endpoint and all secondary endpoints in patients with episodic migraine who had experienced two to four previous preventive treatment failures due to lack of efficacy or intolerable side effects.

Oncology/Hematology

Aranesp® (darbepoetin alfa)

- In October 2017, we announced that after a recommendation by the data safety monitoring committee, a phase 3 post-marketing requirement study to evaluate the safety and efficacy of Aranesp® in anemic patients with advanced non-small cell lung cancer receiving multi-cycle chemotherapy was terminated early. The study successfully met its primary endpoint of non-inferiority in overall survival compared to placebo, with no new safety findings.

BLINCYTO® (blinatumomab)

- In July 2017, we announced that the FDA approved the sBLA for BLINCYTO® to include overall survival data from the phase 3 TOWER study. The approval converted BLINCYTO®'s accelerated approval to a full approval. The approval expanded the indication of BLINCYTO® for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

- In December 2017, we announced that the FDA accepted for priority review the sBLA for the treatment of minimal residual disease in patients with ALL. The FDA has set a PDUFA target action date of March 29, 2018.

- In February 2018, we announced that the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion recommending a label variation for BLINCYTO® to include overall survival data from the phase 3 TOWER study supporting the conversion of the conditional marketing authorization to a full marketing authorization in adult patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL.

KYPROLIS® (carfilzomib)

- In July 2017, we announced positive results from the final analysis of the phase 3 ASPIRE (CArfilzomib, Lenalidomide, and DexamethaSone versus Lenalidomide and Dexamethasone for the treatment of PatIents with Relapsed Multiple MyEloma) study. The study met the key secondary endpoint of overall survival, demonstrating that KYPROLIS®, lenalidomide and dexamethasone reduced the risk of death by 21% over lenalidomide and dexamethasone alone.

- In October 2017, we announced top-line results of the phase 3 ARROW (RAndomized, Open-label, Phase 3 Study in Subjects with Relapsed and Refractory Multiple Myeloma Receiving Carfilzomib in Combination with Dexamethasone, Comparing Once-Weekly versus Twice-weekly Carfilzomib Dosing) study, which showed KYPROLIS® administered once-weekly at the 70 mg/m^2 dose with dexamethasone allowed relapsed and refractory multiple myeloma patients to live 3.6 months longer without their disease worsening than KYPROLIS® administered twice-weekly at the 27 mg/m^2 dose with dexamethasone. The overall safety profile of the once-weekly KYPROLIS® regimen was comparable to that of the twice-weekly regimen.

- In December 2017, we submitted a supplemental New Drug Application (sNDA) to the FDA and a variation to the Marketing Authorization to the EMA to include the overall survival data from the ASPIRE study in the product label.

- In January 2018, we announced that the FDA approved the sNDA to add overall survival data from the phase 3 head-to-head ENDEAVOR study to the prescribing information for KYPROLIS®.

- In January 2018, we announced that the CHMP of the EMA adopted a positive opinion recommending a label variation for KYPROLIS® to include updated overall survival data from the phase 3 head-to-head ENDEAVOR (RandomizEd, OpeN Label, Phase 3 Study of Carfilzomib Plus DExamethAsone Vs Bortezomib Plus DexamethasOne in Patients With Relapsed Multiple Myeloma) study in patients with relapsed or refractory multiple myeloma. The ENDEAVOR study demonstrated that KYPROLIS® and dexamethasone reduced the risk of death by 21 percent, and increased overall survival by 7.6 months versus VELCADE® (bortezomib) and dexamethasone.

Vectibix® (panitumumab)

- In June 2017, we announced that the FDA approved the sBLA for Vectibix® to more precisely define patients with wild-type *RAS* metastatic colorectal cancer, as first-line therapy in combination with FOLFOX and as monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin and irinotecan-containing chemotherapy.

Nephrology

Sensipar®/Mimpara® (cinacalcet)

- In August 2017, we announced that the EC granted Marketing Authorization of a pediatric formulation (granules in capsule for opening) of Mimpara® for the treatment of secondary hyperparathyroidism (sHPT) in children aged three years and older with end-stage renal disease on maintenance dialysis therapy in whom sHPT is not adequately controlled with standard of care therapy.

Biosimilars

AMJEVITA™ (adalimumab-atto) / AMGEVITA™ (biosimilar adalimumab)

- In March 2017, we announced that the EC granted market authorization for AMGEVITA™, a biosimilar to AbbVie's HUMIRA®, in all available indications.

- In September 2017, we announced that we have reached a global settlement with AbbVie to resolve all pending litigation regarding AMJEVITA™/AMGEVITA™. Under terms of the agreement, AbbVie will grant patent licenses for the use and sale of AMJEVITA™/AMGEVITA™ worldwide, on a country-by-country basis, and the companies have agreed to dismiss all pending patent litigation. We expect to launch AMGEVITA™ in Europe in October 2018 and AMJEVITA™ in the United States in January 2023.

ABP 980

- In March 2017, we announced the submission of a MAA to the EMA for ABP 980, a biosimilar candidate to Herceptin® (trastuzumab). ABP 980 is being developed in collaboration with Allergan plc (Allergan).

- In October 2017, we announced that the FDA accepted for review a BLA for ABP 980. The FDA has set a Biosimilar User Fee Act target action date of May 28, 2018.

MVASI™ (bevacizumab-awwb)

- In September 2017, we announced that the FDA approved MVASI™ for all eligible indications of the reference product, Avastin®. MVASI™ is the first anti-cancer biosimilar, as well as the first bevacizumab biosimilar, approved by the FDA. MVASI™ is approved for the treatment of five types of cancer. MVASI™ is being developed in collaboration with Allergan.

- In January 2018, we announced that the EC granted marketing authorization for MVASI™ (biosimilar bevacizumab) for the treatment of certain types of cancers.

Next-generation biomanufacturing

- In May 2017, our next-generation biomanufacturing plant in Singapore was approved by the FDA for certain commercial production.

2017 U.S. Tax Reform

- On December 22, 2017, the United States enacted major tax reform legislation, Public Law No. 115-97, commonly referred to as the Tax Cuts and Jobs Act (2017 Tax Act). The 2017 Tax Act imposes a repatriation tax on accumulated earnings of foreign subsidiaries, implements a territorial tax system together with a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. See Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

Offer to Purchase Common Stock

- On February 5, 2018, we announced a tender offer to purchase up to $10 billion of our common stock at a price not greater than $200 per share nor less than $175 per share. The tender is based on our confidence in the long-term outlook for our business, enhanced by the 2017 Tax Act, and is consistent with our ongoing objective to return capital to our stockholders. The tender offer expires at 12:00 Midnight, New York City time, at the end of Monday, March 5, 2018, unless the offer is extended.

* FDA provisionally approved trade name

Marketing, Distribution and Selected Marketed Products

The largest concentration of our sales and marketing forces is based in the United States and Europe. Additionally, we continue to expand the commercialization and marketing of our products into other geographic territories, including parts of Latin America, the Middle East and Asia. This expansion is occurring by establishing our own affiliates, by acquiring existing third-party businesses or product rights or by partnering with third parties.

Whether we use our own sales and marketing forces or a third-party's varies across these markets. Such use typically depends on several factors, including the nature of entry into the new market, the size of an opportunity and operational capabilities. Together with our partners, we market our products to healthcare providers, including physicians or their clinics, dialysis centers, hospitals and pharmacies.

In the United States, we sell primarily to pharmaceutical wholesale distributors that are the principal means of distributing our products to healthcare providers. We also market certain products directly to consumers through several direct-to-consumer channels, including print, television and online media, as well as through multi-channel marketing. For further discussion, see

Government Regulation—Regulation of Product Marketing and Promotion. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country.

Our product sales to three large wholesalers, AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc., each individually accounted for more than 10% of total revenues for each of the years ended December 31, 2017, 2016 and 2015. On a combined basis, these wholesalers accounted for 96%, 96% and 97% of our U.S. gross product sales, for each of the years ended December 31, 2017, 2016 and 2015, respectively, and 81% of worldwide gross revenues for each of these years. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

For financial information related to our one business segment, see Part IV—Consolidated Statements of Income, Consolidated Balance Sheets, and Note 19, Segment information, to the Consolidated Financial Statements.

Our products are marketed around the world with the United States being our largest market. The following chart shows our product sales by principal product and by geography for the years ended 2017, 2016 and 2015.

a2017productsalesgrapha01.jpg

Enbrel® (etanercept)

We market ENBREL primarily in the United States. It was launched in 1998 and is used primarily in indications for the treatment of adult patients with the following conditions:

- moderately to severely active rheumatoid arthritis,
- chronic moderate-to-severe plaque psoriasis patients who are candidates for systemic therapy or phototherapy, and
- active psoriatic arthritis.

Neulasta® (pegfilgrastim)

We market Neulasta®, a pegylated protein based on the filgrastim molecule, primarily in the United States and Europe. Neulasta® was launched in 2002, and is used primarily in the indication to help reduce the chance of infection due to a low white blood cell count, in patients with certain types of cancer (non-myeloid) who receive anti-cancer medicines (chemotherapy) that can cause fever and a low blood cell count. In 2015, the Neulasta® Onpro® kit became available in the United States. The Neulasta® Onpro® kit provides patients the opportunity to administer the recommended dose of Neulasta® at home the day after chemotherapy, saving a trip back to the doctor.

Aranesp® (darbepoetin alfa)

We market Aranesp® primarily in Europe and the United States. It was launched in 2001, and is indicated to treat a lower-than-normal number of red blood cells (anemia) caused by chronic kidney disease (CKD) (in both patients on dialysis and patients not on dialysis). Aranesp® is also indicated for the treatment of anemia due to concomitant myelosuppressive chemotherapy in patients with non-myeloid malignancies, and when chemotherapy will be used for at least two months after starting Aranesp®.

Aranesp® and EPOGEN® compete with each other in the United States, primarily in the dialysis setting.

Prolia® (denosumab)

We market Prolia® primarily in the United States and Europe. Prolia® contains the same active ingredient as XGEVA® but is approved for different indications, patient populations, doses and frequencies of administration. Prolia® was launched in the United States and Europe in 2010. In the United States, it is used primarily in the indication for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In Europe, Prolia® is used primarily for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Sensipar®/Mimpara® (cinacalcet)

We market cinacalcet as Sensipar® primarily in the United States and as Mimpara® primarily in Europe. It was launched in 2004 and is used primarily in the indication for the treatment of sHPT in adult patients with CKD who are on dialysis.

XGEVA® (denosumab)

We market XGEVA® primarily in the United States and Europe. XGEVA® was launched in the United States in 2010, and is used primarily in the indication for the prevention of SREs (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumors, including multiple myeloma. XGEVA® was launched in Europe in 2011, and is used primarily in the indication for the prevention of SREs in patients with bone metastases from solid tumors, and was recently approved for the prevention of SREs in patients with multiple myeloma.

EPOGEN® (epoetin alfa)

We market EPOGEN® in the United States for dialysis patients. EPOGEN® was launched in 1989, and we market it for the indication to treat anemia caused by CKD in patients on dialysis to lessen the need for red blood cell transfusions. The majority of our sales are to a large dialysis provider.

Other Marketed Products

We also market a number of other products, including KYPROLIS® (carfilzomib), Vectibix® (panitumumab), Nplate® (romiplostim), NEUPOGEN® (filgrastim), Repatha® (evolocumab), BLINCYTO® (blinatumomab), IMLYGIC® (talimogene laherparepvec), Corlanor® (ivabradine) and Parsabiv™ (etelcalcetide).

Patents

The following table describes our outstanding material patents for the indicated product by territory, general subject matter and latest expiry date. Certain of the European patents are the subject of supplemental protection certificates that provide additional protection for the product in certain European countries beyond the dates listed in the table (see footnotes).

One or more patents with the same or earlier expiry date may fall under the same "general subject matter" and are not listed separately.

Product	Territory	General subject matter	Expiration
Enbrel® (etanercept)	U.S.	Methods of treating psoriasis	8/13/2019
	U.S.	Aqueous formulation and methods of treatment using the formulation	6/8/2023
	U.S.	Fusion protein, and pharmaceutical compositions	11/22/2028
	U.S.	DNA encoding fusion protein, and methods of making fusion protein	4/24/2029
Aranesp® (darbepoetin alfa)	U.S.	Glycosylation analogs of erythropoietin proteins	5/15/2024
Prolia®/ XGEVA® (denosumab)	U.S.	RANKL antibodies; and methods of use(1)	12/22/2017
	U.S.	Methods of treatment	6/25/2022
	U.S.	Nucleic acids encoding RANKL antibodies, and methods of producing RANKL antibodies	11/30/2023
	U.S.	RANKL antibodies including sequences	2/19/2025
	Europe	Medical use of RANKL antibodies	4/15/2018
	Europe	RANKL antibodies including epitope binding	2/23/2021
	Europe	RANKL antibodies including sequences(2)	6/25/2022
Sensipar®/ Mimpara® (cinacalcet)	U.S.	Calcium receptor-active molecules	3/8/2018
	U.S.	Formulation	9/22/2026
	Europe	Calcium receptor-active molecules(2)	10/23/2015
KYPROLIS® (carfilzomib)	U.S.	Compositions and compounds	12/7/2027
	U.S.	Methods of treatment	4/14/2025
	Europe	Compositions, compounds and methods of treatment(2)	8/8/2025
Vectibix® (panitumumab)	U.S.	Human monoclonal antibodies to epidermal growth factor receptor (EGFr)	4/8/2020
	Europe	Human monoclonal antibodies to EGFr(2)	5/5/2018
Nplate® (romiplostim)	U.S.	Thrombopoietic compounds	1/19/2022
	U.S.	Formulation	2/12/2028
	Europe	Thrombopoietic compounds(2)	10/22/2019
	Europe	Formulation	4/20/2027
Repatha® (evolocumab)	U.S.	Antibodies(3)	10/25/2029
	U.S.	Methods of treatment	10/8/2030
	Europe	Compositions and method of treatment	8/22/2028
BLINCYTO® (blinatumomab)	U.S.	Bifunctional polypeptides(3)	4/21/2019
	U.S.	Method of administration	9/28/2027
	Europe	Bifunctional polypeptides(2)	11/26/2024
	Europe	Method of administration	11/29/2026
IMLYGIC® (talimogene laherparepvec)	U.S.	Compositions and method of treatment(3)	1/22/2021
	Europe	Composition and uses(2)	1/22/2021
Parsabiv™ (etelcalcetide)	U.S.	Compound and pharmaceutical composition	7/29/2030
	Europe	Compound and pharmaceutical composition	7/29/2030

(1) The U.S. Patent and Trademark Office has issued a Notice of Final Determination that a patent with this subject matter is eligible for patent term extension with an expiry of September 17, 2021.

(2) A European patent with this subject matter may also be entitled to supplemental protection in one or more countries in Europe, and the length of any such extension will vary by country. For example, supplementary protection certificates have been issued related to the indicated products for patents in at least the following countries:

- denosumab — France, Italy, Spain and the United Kingdom, expiring in 2025
- cinacalcet — France, Germany, Spain and the United Kingdom, expiring in 2019; and Italy, expiring in 2020
- carfilzomib — France, Germany, Italy and Spain, expiring in 2030
- panitumumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2022
- romiplostim — France, Germany, Italy, Spain and the United Kingdom, expiring in 2024
- blinatumomab — France, Italy and Spain, expiring in 2029
- talimogene laherparepvec — Italy, expiring in 2026

(3) A patent with this subject matter may be entitled to patent term extension in the United States.

Competition

We operate in a highly competitive environment. A number of our marketed products are indicated in disease areas where other products or treatments are currently available or are being pursued by our competitors through research and development (R&D) activities. We continue to pursue ways to increase the value of our medicines through innovations during their lifecycles. This can include expanding the disease areas for which our products are indicated and finding new methods to make the delivery of our medicines easier and less costly. Such activities can offer important opportunities for differentiation. For example, in 2015, we launched the Neulasta® Onpro® kit, which provides patients the opportunity to administer the recommended dose of Neulasta® at home the day after chemotherapy, thereby saving a trip back to the doctor. We also developed the AutoTouch™ reusable auto-injector to be used with Enbrel Mini™ single-dose prefilled cartridges (50 mg/mL), which was approved by the FDA in September 2017. The Enbrel Mini™ utilizes a new drug formulation of ENBREL that was associated with substantially significant lower mean injection site pain than the current formulation. We plan to continue pursuing such innovation efforts to strengthen our competitive position. Such position may be based on, among other things, safety, efficacy, reliability, availability, patient convenience/delivery devices, price, reimbursement, access to and timing of market entry and patent position and expiration.

Certain of the existing patents on our principal products have expired, and we face new and increasing competition, including from biosimilars and generics. We may also compete against biosimilar or generic versions of our competitors' products. A biosimilar is another version of a biological product for which marketing approval is sought or has been obtained based on a demonstration that it is "highly similar" to the original reference product. See Government Regulation. We expect that the adverse impact from biosimilars will be more like branded biologic competition than that seen when branded small molecules face generics. Although we expect biosimilars to compete on price, we believe many patients, providers and payers will continue to place high value on the reputation, reliability and safety of our products. Zarxio®, a biosimilar version of NEUPOGEN® from Sandoz, a Novartis company (Sandoz), which launched in the United States in 2015, was the first biosimilar entrant into the U.S. market. Companies have pending applications with the FDA for biosimilar versions of EPOGEN® and Neulasta®, along with additional biosimilar versions of NEUPOGEN®. See also Government Regulation—Regulation in the United States —Approval of Biosimilars. As biosimilar competitors come to market, we will leverage both the experience we have had in the United States versus branded competition, and our experience in competing against epoetin alfa and filgrastim biosimilars in Europe.

The introduction of new products, the development of new processes or technologies by competitors or the emergence of new information about existing products may result in increased competition for our marketed products, even for those protected by patents, or in reductions in the prices we receive from selling our products. In addition, the development of new treatment options or standards of care may reduce the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates. (As used in this document, the term *clinical trials* may include prospective clinical trials, observational studies, registries and other studies.) See

Item 1A. Risk Factors—*Our products face substantial competition* and Item 1A. Risk Factors—*We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future*.

The following table reflects our significant competitors and is not exhaustive.

Product	Territory	Competitor marketed product	Competitors
ENBREL	U.S. & Canada	REMICADE®*	Janssen Biotech, Inc. (Janssen)(1)
	U.S. & Canada	HUMIRA®	AbbVie Inc.
	U.S. & Canada	STELARA®(2)	Janssen(1)
	U.S. & Canada	Otezla®(2)	Celgene Corporation (Celgene)
Neulasta®(3)	Europe	Filgrastim biosimilars	Various
Aranesp®	U.S.	PROCRIT®(4)	Janssen(1)
	U.S.	MIRCERA®(5)	Galenica Group (Galenica)/F. Hoffmann-La Roche Ltd. (Roche)
	Europe	Epoetin alfa biosimilars	Various
Prolia®	U.S. & Europe	Alendronate, raloxifene and zoledronate generics	Various
Sensipar®(6)/ Mimpara®	U.S. & Europe	Active vitamin D analogs	Various
XGEVA®	U.S. & Europe	Zoledronate generics	Various
EPOGEN®(3)	U.S.	MIRCERA®(5)	Galenica/Roche
KYPROLIS®(8)	U.S.	VELCADE®	Millennium Pharmaceuticals, Inc.(7)
	U.S.	REVLIMID®	Celgene
	U.S.	POMALYST®	Celgene
	U.S.	DARZALEX®	Janssen(1)
Repatha®	U.S. & Europe	PRALUENT®	Regeneron Sanofi

* Approved biosimilars available.

(1) A subsidiary of Johnson & Johnson (J&J).

(2) Dermatology only.

(3) Biosimilars under regulatory review in the United States.

(4) PROCRIT® competes with Aranesp® in the supportive cancer care and pre-dialysis settings.

(5) MIRCERA® competes with Aranesp® only in the nephrology segment.

(6) Our U.S. composition of matter patent for Sensipar® expires in March 2018. We are engaged in litigation with a number of companies seeking to market generic versions of Sensipar® surrounding our U.S. formulation patent that expires in September 2026. See Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements, for further information. Several of these generic versions of Sensipar® have been tentatively approved by the FDA.

(7) A subsidiary of Takeda Pharmaceutical Company Limited.

(8) KYPROLIS® is facing increased competition from several recently approved products.

Reimbursement

Sales of our principal products are dependent on the availability and extent of coverage and reimbursement from third-party payers. In many markets around the world, these payers, including government health systems, private health insurers and other organizations, remain intensely focused on reducing the cost of healthcare. Their

efforts have intensified as a result of rising healthcare costs and economic challenges. Drugs, and in particular specialty drugs such as our products, remain heavily scrutinized for cost containment. As a result, payers are being more restrictive regarding the use of biopharmaceutical products, while requiring a higher level of clinical evidence to support the benefit such products bring to patients and the broader healthcare system.

In the United States, biopharmaceutical product pricing remains central to discussions on controlling healthcare costs. The pricing practices of certain companies have increased public media and government scrutiny of the biopharmaceutical industry,

providing greater incentive for governments and private payers to limit or regulate the prices of drug products and services. Policymakers from both major U.S. political parties, including key members of the presidential administration, have indicated their support for pursuing policies to lower drug costs for patients. At the same time, value assessments of new technologies, previously used predominantly outside the United States, are having an impact in the U.S. healthcare environment. Healthcare provider organizations and independent organizations are creating their own value assessments of biopharmaceutical drugs for comparison with manufacturer pricing. Although these organizations do not set drug prices, they seek to influence pricing as well as payer and provider decision making by publicly disclosing their assessments, often making assertions around what they believe to be the appropriate price to charge for a product. In addition, continued consolidation of payers and integration of providers and payers (integrated delivery systems) increase the level of market power held by our customers. These developments put greater pressure on access to, pricing of and sales of our products.

In the United States, healthcare providers are reimbursed for covered services and products they deliver through Medicare, Medicaid and other government healthcare programs, as well as through private payers. Pharmacies are also reimbursed in a similar manner for drug products they dispense. We are required to provide rebates or discounts on our products that are reimbursed through certain government programs, including Medicare and Medicaid, and also provide discounts to qualifying health care providers under the Federal 340B Drug Pricing Program. These rebates and/or discounts levels, as well as entities who are entitled to receive them, have increased over time. For example, the Patient Protection and Affordable Care Act (ACA), enacted in 2010, increased many of the mandatory discounts and rebates required of us. The ACA also imposed a new Branded Prescription Pharmaceutical Manufacturers and Importers fee payable each year by us and other manufacturers. The U.S. presidential administration has identified repealing and replacing the ACA as a priority. In the tax reform bill signed by President Trump in December 2017, Congress removed a key ACA provision by repealing the individual mandate penalty which required each individual to have health insurance or pay a penalty. Future changes to government programs such as the ACA, whether legislative or regulatory, could impact the number of patient lives covered, could raise or lower the cost of quality insurance, could affect Medicaid eligibility and could change levels of patient protections provided unless alternatives are put in place.

Additional efforts by state legislatures and government agencies in the United States could also affect us and our industry. For example, a recently enacted California law requires manufacturers to provide payers advance notice of a price increase over a specified threshold, and a Vermont law requires manufacturers to submit price increase justifications to the state attorney general if certain price increase and state-spending thresholds are met. Examples of other proposals that have been discussed and debated, but not yet enacted, include state ballot initiatives that would place a maximum price ceiling, or cap, on pharmaceutical products purchased by state agencies and state legislative efforts to cap pharmaceutical prices for commercial payers. Other government legislative and regulatory actions that would have a significant impact on Amgen include: changes to how the Medicare program covers and reimburses current and future drugs, including for patients with End-Stage Renal Disease; changes in the Federal payment rate or new rebate requirements for covered drugs and policies for drug payment in Medicare or Medicaid; and changes to coverage and payment for biosimilars, such as policies that would enable easier substitution for, or provide reimbursement advantages over, the corresponding innovative products. Centers for Medicare & Medicaid Services (CMS) has indicated interest in testing new models for drug payment in Medicare Part B and Part D. CMS also continues to test alternative payment models with providers, such as the Oncology Care Model. These models provide financial incentives to providers who participate under which providers take on greater risk for the overall cost and quality of care. In addition, CMS recently finalized changes to Medicare payment to hospitals for Part B drugs acquired through the Federal 340B Drug Pricing Program but provide financial incentive for hospitals to use biosimilar products over the corresponding innovative products. CMS is also proposing changes to Medicare Part D and Medicare Advantage. These and/or other changes have the potential to impact prescribing and patient access to Amgen's therapies.

In the U.S. private sector, payers continue to institute cost reduction and containment measures that lower drug utilization and/or spending altogether and/or shift a greater portion of the costs to patients. Such measures include more limited benefit plan designs, higher patient co-pays or coinsurance obligations, limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs), higher-tier formulary placement that increases the level of patient out-of-pocket costs and/or stricter utilization management criteria before a patient may get access to a drug. In the specialty pharmacy sector, in which the majority of our sales for ENBREL and Repatha® occur, the use of such measures by Pharmacy Benefit Managers (PBMs) and insurers has continued to intensify which have limited Amgen product usage and sales. PBMs are third-party organizations tasked with administrating prescription drug programs for large employers, health plans and government programs. Consolidation has resulted in a smaller number of PBMs and insurers overseeing a large

portion of total covered lives in the United States. As a result, PBMs and insurers have greater market power and negotiating leverage to exclude drugs from their formularies in favor of competitor drugs or alternative treatments, and/or to mandate stricter utilization criteria. Formulary exclusion effectively encourages patients and providers to seek alternative treatments or pay 100% of the cost of a drug. Our experience with Repatha® underscores that utilization management requirements, including the burdensome administrative processes required of physicians to demonstrate and document that patients meet such requirements, continue to be a significant challenge for patients and physicians, limiting access for appropriate usage. Even when access is available, some patients abandon their prescriptions due to economic reasons. In highly competitive treatment markets such as

with ENBREL and Repatha®, PBMs are also able to exert negotiating leverage by requiring incremental rebates from manufacturers in order to maintain their formulary position. A drug's inclusion and favorable positioning on formulary is essential to ensure patients have access.

In many countries outside the United States, government-sponsored healthcare systems are the primary payers for drugs and biologics. With increasing budgetary constraints, payers in many countries are applying a variety of measures to exert downward price pressure. These measures can include mandatory price controls, price referencing, therapeutic reference pricing, increases in mandates or incentives for generic substitution and biosimilar usage, and government-mandated price cuts. In this regard, many countries have Health Technology Assessment (HTA) organizations that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies, and these organizations are expanding in established and emerging markets. We expect that countries will continue to take aggressive actions to seek to reduce expenditures on drugs and biologics. Similarly, fiscal constraints may also impact the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

The dynamics and developments discussed above serve to create pressure on the pricing and potential usage of our products, and the industry as a whole. We remain focused on delivering breakthrough treatments for unmet medical needs. Amgen is committed to working with the entire healthcare community to ensure continued innovation and to enable patient access to needed medicines. We do this by:

- investing billions of dollars annually in R&D;
- developing more affordable therapeutic choices in the form of high-quality and reliably-supplied biosimilars;
- pricing our medicines to reflect the value they provide;
- partnering with payers to share risk and accountability for health outcomes;
- providing patient support and education programs and helping patients in financial need access our medicines; and
- working with policymakers, patients and other stakeholders to establish a sustainable healthcare system with access to affordable care and where patients and their healthcare professionals are the primary decision makers.

See Item 1A. Risk Factors—*Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability* and Item 1A. Risk Factors—*Guidelines and recommendations published by various organizations can reduce the use of our products.*

Manufacturing, Distribution and Raw Materials

Manufacturing

We believe we are a leader in the manufacturing of biologics and that our manufacturing capabilities represent a competitive advantage. The products we manufacture consist of both biologics and small molecule drugs. The majority of our products are biologics that are produced in living cells and that are inherently complex due to naturally-occurring molecular variations. Highly specialized knowledge and extensive process and product characterization are required to transform laboratory-scale processes into reproducible commercial manufacturing processes. Further, our expertise in manufacturing of biologics positions us well for leadership in the global biosimilars market. For additional information regarding manufacturing facilities, see Item 2. Properties.

Our internal manufacturing network has the commercial production capabilities of bulk manufacturing, formulation, fill, finish and device assembly. These activities are performed within the United States and its territories in our Puerto Rico, Rhode Island and California facilities, as well as internationally in our Ireland, Netherlands and Singapore facilities. In addition, we utilize third-party contract manufacturers to supplement our commercial manufacturing requirements. We utilize these internal facilities and third-party contract manufacturers to develop similar capabilities in multiple geographic areas to mitigate potential supply impacts of the most important risks facing our supply chain.

In September 2017, Hurricane Maria made landfall on the island of Puerto Rico causing some damage to our facility in Juncos. Critical manufacturing areas of our facility were not significantly affected, and we have resumed our full manufacturing operations. Further recovery efforts on the island are ongoing. We have continued to provide an uninterrupted supply of medicines for patients around the world.

We manufacture products to support our clinical trials primarily at our California and Rhode Island facilities. We also utilize third-party contract manufacturers for certain clinical products.

See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

Distribution

We operate distribution centers in Kentucky, California and the Netherlands for worldwide distribution of the majority of our commercial and clinical products. We also use third-party distributors to supplement distribution of our products worldwide.

Other

In addition to the manufacturing and distribution activities noted above, our operations in the United States, the U.S. territory of Puerto Rico and the Netherlands include key manufacturing support functions, including quality control, process development, procurement, production scheduling and warehousing. Certain of those manufacturing and distribution activities are highly regulated by the FDA as well as other international regulatory agencies. See Government Regulation—Regulation in the United States—Regulation of Manufacturing Standards.

Manufacturing Initiatives

We have multiple ongoing initiatives that are designed to extend our manufacturing advantage by optimizing our manufacturing network and/or mitigating risks while continuing to ensure adequate supply of our products. In 2017, our new biologics manufacturing facility in Singapore was licensed by the FDA and EMA for certain commercial scale production. The Singapore facility was completed in approximately half the time typically required for conventional biomanufacturing equivalents. It utilizes a flexible and modular design that can be replicated in future facilities, enabling higher production and accessibility to patients around the world. The Singapore facility is fully reconfigurable, allowing the production of other products for worldwide supply. For example, in October 2017, we completed a second bulk process qualification campaign, which, if approved, would enable a second molecule to be manufactured at that facility. We also completed the construction of a second facility in Singapore and we are currently carrying out a qualification campaign.

See Item 1A. Risk Factors—*Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

Raw Materials and Medical Devices

Certain raw materials, medical devices (including companion diagnostics) and components necessary for the commercial and/or clinical manufacturing of our products are provided by and are the proprietary products of unaffiliated third-party suppliers, certain of which may be our only sources for such materials. We currently attempt to manage the risk associated with such suppliers by inventory management, relationship management and evaluation of alternative sources when feasible. We also monitor the financial condition of certain suppliers and their ability to supply our needs. See Item 1A. Risk Factors—*We rely on third-party suppliers for certain of our raw materials, medical devices and components.*

We perform various procedures to help authenticate the source of raw materials, including intermediary materials used in the manufacture of our products, which include verification of the country of origin. The procedures are incorporated into the manufacturing processes we and our third-party contract manufacturers perform.

Government Regulation

Regulation by government authorities in the United States and other countries is a significant factor in the production and marketing of our products and our ongoing R&D activities. In order to clinically test, manufacture and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. Compliance with these standards is complex and failure to comply with any of these standards can result in significant implications. See Item 1A. Risk Factors for a discussion of factors that can adversely impact our development and marketing of commercial products including global regulatory implications.

Regulation in the United States

In the United States, the Public Health Service Act, the Federal Food, Drug, and Cosmetic Act (FDCA) and the regulations promulgated thereunder, as well as other federal and state statutes and regulations govern, among other things, the production, research, development, testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising and promotion, and distribution of our products, as well as the reporting of certain payments and other transfers of value to healthcare professionals and teaching hospitals.

Clinical Development and Product Approval. Drug development in our industry is complex, challenging and risky; and failure rates are high. Product development cycles are typically very long—approximately 10 to 15 years from discovery to market. A potential new medicine must undergo many years of preclinical and clinical testing to establish its safety and efficacy for use in humans at appropriate dosing levels and with an acceptable risk-benefit profile.

After laboratory analysis and preclinical testing in animals, we file an Investigational New Drug Application (IND) with the FDA to begin human testing. Typically, we undertake an FDA-designated three-phase human clinical testing program.

- In phase 1, we conduct small clinical trials to investigate the safety and proper dose ranges of our product candidates in a small number of human subjects.

- In phase 2, we conduct clinical trials to investigate side-effect profiles and the efficacy of our product candidates in a large number of patients who have the disease or condition under study.

- In phase 3, we conduct clinical trials to investigate the safety and efficacy of our product candidates in a large number of patients who have the disease or condition under study.

The FDA monitors the progress of each trial conducted under an IND and may, at its discretion, reevaluate, alter, suspend or terminate the testing based on the data accumulated to that point and the FDA's risk benefit assessment with regard to the patients enrolled in the trial. The results of preclinical and clinical trials are submitted to the FDA in the form of a BLA for biologic products or an New Drug Application for small molecule products. We are not permitted to market or promote a new product until the FDA has approved our marketing application.

Approval of Biosimilars. The ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. The pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on the non-clinical and clinical trial data of an originator product to which the biosimilar has been demonstrated to be "highly similar" and to have no clinically meaningful differences in terms of safety, purity and potency. The relevance of demonstrating "similarity" is that in many cases, biosimilars can be brought to market without conducting the full suite of clinical trials typically required of originators, as risk-benefit has previously been established. In order to preserve incentives for future innovation, the law establishes a period of exclusivity for originators' products, which in general prohibits biosimilars from gaining FDA approval based in part on reliance on or reference to the originator's data in their application to the FDA for 12 years after FDA approval of the originator product. The law does not change the duration of patents granted on biologic products. The FDA has released a number of guidance documents as part of the implementation of the abbreviated approval pathway for biosimilars, some of which remain in draft form. As of the end of 2017, seven biosimilar applications have been approved by the FDA, including our products AMJEVITA™ and MVASI™, as well as competitors to our products ENBREL and NEUPOGEN®. A number of manufacturers have announced the filing of marketing applications to the FDA under the biosimilar pathway, some of which are for biosimilars of our products.

Regulation of Product Marketing and Promotion. The FDA regulates the marketing and promotion of products. Our product promotion for approved product indications must comply with the statutory standards of the FDCA and the FDA's implementing regulations and standards. The FDA's review of marketing and promotional activities encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA may also review industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. The FDA may take enforcement action against a company for promoting unapproved uses of a product or for other violations of its advertising and labeling laws and regulations. Enforcement action may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with the FDA's regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators. Additionally, as described below, such failure may lead to additional liability under U.S. health care fraud and abuse laws.

Regulation of Manufacturing Standards. The FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of products prior to providing approval to market products. If after receiving approval from the FDA, we make a material change in manufacturing equipment, location or process,

additional regulatory review may be required. We also must adhere to current Good Manufacturing Practice regulations and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA conducts regular, periodic visits to re-inspect our equipment, facilities, laboratories and processes following an initial approval.

Regulation of Combination Products. Combination products are defined by the FDA to include products composed of two or more regulated components (e.g., a biologic and/or drug and a device). Biologics/Drugs and devices each have their own regulatory requirements, and combination products may have additional requirements. A number of our marketed products meet this definition and are regulated under this framework, and we expect that a number of our pipeline product candidates will be evaluated for regulatory approval under this framework as well.

Regulation Outside the United States

In the European Union (EU) countries as well as Switzerland, Canada, Australia and Japan, regulatory requirements and approval processes are similar in principle to those in the United States.

In the EU, there are currently two potential tracks for seeking marketing approval for a product which is not authorized in any Member State; a decentralized procedure and a centralized procedure. In the decentralized procedure, identical applications for marketing authorization are submitted simultaneously to the national regulatory agencies. Regulatory review is led by one Member State (the Reference Member State) and its assessment—based on safety, quality and efficacy—is reviewed and approved (assuming there are no concerns that the product poses a serious risk to public health) by the other Member States from which the applicant is seeking approval (the Concerned Member States). The decentralized procedure leads to a series of single national approvals in all relevant countries. In the centralized procedure, which is required of all products derived from biotechnology, a company submits a single MAA to the EMA, which conducts an evaluation of the dossier, drawing upon its scientific resources across Europe. If the drug product is proven to fulfill the requirements for quality, safety and efficacy, the EMA's CHMP adopts a positive opinion, which is transmitted to the EC for final decision on grant of the marketing authorization. While the EC generally follows the CHMP's opinion, it is not bound to do so. Subsequent commercialization is enabled by country-by-country reimbursement approval.

In the EU, biosimilars are approved under a specialized pathway of the centralized procedure. As with the U.S. pathway, applicants seek and obtain regulatory approval for a biosimilar once the data exclusivity period for the original reference product has expired relying in part on the data submitted for the originator product together with data evidencing that the biosimilar is "highly similar" in terms of quality, safety and efficacy to the original reference product authorized in the European Economic Area.

As a result of the vote by the United Kingdom (UK) to leave the EU in March 2019, the EMA announced on November 20, 2017 that it will relocate its headquarters from London to Amsterdam by March 30, 2019. In addition to uncertainty regarding the supervision and regulation of our products in the UK, it is unclear what impact the EMA move will have on the EU marketing approval process.

Other countries such as Russia, Turkey and those in Latin America and the Middle East have review processes and data requirements similar to those of the EU, and in some cases can rely on prior marketing approval from U.S. or EU regulatory authorities. The regulatory process in these countries may include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements.

In Asia Pacific, a number of countries such as China, Japan, South Korea and Taiwan may require local clinical trial data for bridging purposes as part of the drug registration process in addition to global clinical trials, which can add to overall drug development and registration timelines. In most of the Asian markets, registration timelines depend on marketing approval in the United States or the EU. In some markets in Asia, such as China, Thailand and Indonesia, the regulatory timelines can be less predictable. The regulatory process may also include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements. Countries such as Australia and Japan have more mature systems that would allow for submissions in more competitive timeframes. Regarding biosimilars, several of these countries have pathways to register biosimilars (e.g., South Korea, India, Australia, Singapore and Taiwan) and biosimilar products are already present on the markets (e.g., Australia and South Korea).

In some countries, such as Japan and those in the EU, medical devices may be subject to regulatory regimes whereby the manufacturer must establish that its medical device conforms to essential requirements set out in the law for the particular device category. For example, in the EU, with limited exceptions, medical devices placed on the market must bear the Conformité Européenne marking to indicate their conformity with legal requirements.

Post-approval Phase

After approval, we continue to monitor adverse events and product complaints reported following the use of our products through routine post-marketing surveillance and studies when applicable. We report such events to the appropriate regulatory agencies, as required per local regulations for individual cases and aggregate reports. We proactively monitor (according to good pharmacovigilance practices) and ensure implementation of signal detection, assessment and the communication of adverse events that may be associated with the use of our products. We also proactively monitor product complaints through our quality systems, which includes assessing our drug delivery devices for device complaints, adverse events and malfunctions. We may also be required by regulatory agencies to conduct further clinical trials on our marketed products as a condition of their approval or to provide additional information on safety and efficacy. Health authorities, including the FDA, have authority to mandate labeling

changes to products at any point in a product's lifecycle based on new safety information or as part of an evolving label change to a particular class of products.

Health authorities, including the FDA, also have the authority, before or after approval, to require companies to implement a risk management program for a product to ensure that the benefits of the drug outweigh the risks. Each risk management program is unique and varies depending on the specific factors required. In the United States, a risk management program is known as a risk evaluation and mitigation strategy (REMS) and we currently have REMS for Prolia®, Nplate® and BLINCYTO®.

Other Regulation

We are also subject to various laws pertaining to healthcare "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for or to induce the referral of business, including the purchase or prescription of a particular drug that is reimbursed by a state or federal program. False claims laws prohibit knowingly and willingly presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid), any claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as by the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). Liability under the false claims laws may also arise when a violation of certain laws or regulations related to the underlying products (e.g., violations regarding improper promotional activity or unlawful payments) contributes to the submission of a false claim.

In 2012, Amgen announced it had finalized a settlement agreement with the U.S. government and various other parties regarding allegations that Amgen's promotional, contracting, sales and marketing activities and arrangements caused the submission of various false claims under the Federal Civil False Claims Act and various State False Claims Acts. In connection with entering into the settlement agreement, Amgen also entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services that requires Amgen to maintain its corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years. Although the corporate integrity agreement term ended in December 2017, certain of the corporate integrity agreement's reporting obligations to OIG continue into 2018. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that in the future our practices might be further challenged under anti-kickback or similar laws.

Additionally, the U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA arguably includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

Our business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or regulations.

Research and Development and Selected Product Candidates

We focus our R&D on novel human therapeutics for the treatment of serious illness primarily in the areas of oncology/hematology, cardiovascular disease, inflammation, bone health, nephrology and neuroscience. We capitalize on our strength in human genetics, novel biology and protein engineering. We leverage our biologic expertise and take a modality-independent approach to R&D. We use cutting-edge science and technology to study subtle biological mechanisms in search of therapies that will improve the lives of those who suffer from diseases. Our discovery research programs may therefore yield targets that lead to the development of human therapeutics delivered as large molecules, small molecules, other combination modalities or new modalities. Leveraging two decades of research at deCODE, a global leader in analyzing the human genome, we are reshaping our portfolio and increasingly focusing efforts on targets validated in humans. Human genetic validation is used whenever possible in order to enhance the likelihood of success. For the years ended December 31, 2017, 2016 and 2015, our R&D expenses were $3.6 billion, $3.8 billion and $4.1 billion, respectively.

We have major R&D centers in Thousand Oaks and San Francisco, California, Cambridge, Massachusetts, Iceland and in the United Kingdom, as well as smaller research centers and development facilities globally. See Item 2. Properties.

Our clinical trial activities are conducted by both our internal staff and third-party contract clinical trial service providers. To increase the number of patients available for enrollment in our clinical trials, we have opened clinical sites and will continue opening clinical sites and enrolling patients in a number of geographic locations. See

Government Regulation—Regulation in the Unites States—Clinical Development and Product Approval for a discussion of government regulation over clinical development. Also see Item 1A. Risk Factors—*We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.*

Some of our competitors are actively engaged in R&D in areas in which we have products or in which we are developing product candidates or new indications for existing products. For example, we compete with other clinical trials for eligible patients, which may limit the number of available patients who meet the criteria for certain clinical trials. The competitive marketplace for our product candidates is significantly dependent on the timing of entry into the market. Early entry may have important advantages

in gaining product acceptance, thereby contributing to a product's eventual success and profitability. Accordingly, we expect that in some cases, the relative speed with which we can develop products, complete clinical testing, receive regulatory approval and supply commercial quantities of a product to the market will be important to our competitive position.

In addition to product candidates and marketed products generated from our internal R&D efforts, we acquire companies, acquire and license certain product and R&D technology rights and establish R&D arrangements with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. In pursuing these R&D arrangements and licensing or acquisition activities, we face competition from other pharmaceutical and biotechnology companies that also seek to license or acquire technologies, product candidates or marketed products from those entities performing the R&D.

The following table shows a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 12, 2018, unless otherwise indicated. Additional product candidate information can be found on our website at www.amgen.com. (The website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.) The information in this section does not include other, non-registrational clinical trials that we may conduct for purposes other than for submission to regulatory agencies for their approval of a new product indication. We may conduct non-registrational clinical trials for various reasons including to evaluate real-world outcomes or to collect additional safety information with the use of our products. In addition, the table does not include the biosimilar products we are developing, which are discussed later in this section.

Molecule	Disease/condition
Phase 3 Programs	
Aimovig™	Migraine prevention
Aranesp®	Myelodysplastic syndromes
BLINCYTO®	ALL
ENBREL	Psoriatic arthritis; Rheumatoid arthritis remission
EVENITY™	Postmenopausal osteoporosis; Male osteoporosis
IMLYGIC®	Metastatic melanoma
KYPROLIS®	Multiple myeloma
Omecamtiv mecarbil	Chronic heart failure
Prolia®	Glucocorticoid-induced osteoporosis
Tezepelumab	Asthma
AMG 520 / CNP520	Alzheimer's disease
Phase 2 Programs	
BLINCYTO®	Diffuse Large B-Cell Lymphoma (DLBCL)
Tezepelumab	Atopic dermatitis
AMG 301	Migraine prevention
AMG 557	Primary Sjögren's syndrome
AMG 714	Celiac disease
Phase 1 Programs	
IMLYGIC®	Various cancer types
KYPROLIS®	Small-cell lung cancer
Oprozomib	Multiple myeloma
AMG 176	Various cancer types
AMG 224	Multiple myeloma
AMG 330	Acute myeloid leukemia
AMG 420	Multiple myeloma
AMG 570	Systemic lupus erythematosus
AMG 592	Inflammatory diseases
AMG 596	Glioblastoma
AMG 598	Obesity
AMG 673	Acute myeloid leukemia
AMG 701	Multiple myeloma
AMG 757	Small-cell lung cancer
AMG 820	Various cancer types
AMG 966	Inflammatory bowel diseases (Crohn's and ulcerative colitis)
AMG 986	Heart failure

Phase 3 Clinical trials investigate the safety and efficacy of product candidates in a large number of patients who have the disease or condition under study; typically performed with registrational intent.

Phase 2 Clinical trials investigate side effect profiles and efficacy of product candidates in a large number of patients who have the disease or condition under study.

Phase 1 Clinical trials investigate the safety and proper dose ranges of product candidates in a small number of human subjects.

Phase 3 Product Candidate Program Changes

As of February 13, 2017, we had 15 phase 3 programs. As of February 12, 2018, we had 13 phase 3 programs, as three programs were approved, two programs advanced into phase 3 and one program concluded. These changes are set forth in the following table.

Molecule	Disease/condition	Program change
Repatha®	Hyperlipidemia	sBLA approved by FDA
XGEVA®	Cancer-related bone damage in patients with multiple myeloma	sBLA approved by FDA
Vectibix®	Metastatic colorectal cancer for patients with wild-type *RAS*	sBLA approved by FDA
AMG 520 / CNP520	Alzheimer's disease	Advanced to phase 3
Tezepelumab	Severe uncontrolled asthma	Advanced to phase 3
XGEVA®	Delay or prevention of bone metastases in breast cancer	Concluded—study did not meet its primary endpoint

Phase 3 Product Candidate Patent Information

The following table describes our outstanding composition of matter patents that have been issued thus far for our product candidates in phase 3 development that have yet to be approved for any indication. Patents for products already approved for one or more indications but currently undergoing phase 3 clinical trials for additional indications are previously described. See Marketing, Distribution and Selected Marketed Products—Patents.

Molecule	Territory	General subject matter	Estimated expiration*
Aimovig™ (erenumab)			
	U.S.	Polypeptides	2031
	Europe	Polypeptides	2029
EVENITY™ (romosozumab)	U.S.	Polypeptides	2026
	Europe	Polypeptides	2026
Omecamtiv mecarbil	U.S.	Compound	2027
Tezepelumab			
	U.S.	Polypeptides	2029
	Europe	Polypeptides	2028
AMG 520 / CNP520	U.S.	Compound	2032
	Europe	Compound	2032

* Patent expiration estimates are based on issued patents, which may be challenged, invalidated, or circumvented by competitors. The patent expiration estimates do not include any term adjustments, extensions or supplemental protection certificates that may be obtained in the future and extend these dates. Corresponding patent applications are pending in other jurisdictions. Additional patents may be filed or issued and may provide additional exclusivity for the product candidate or its use.

Phase 3 and 2 Program Descriptions

The following text provides additional information about selected product candidates that have advanced into human clinical trials.

Aimovig™

Aimovig™ is a human monoclonal antibody that inhibits the receptor for calcitonin gene-related peptide. It is being evaluated for the prevention of migraine. Aimovig™ is being developed jointly with Novartis.

In July 2017, we announced that the FDA accepted for review the BLA for Aimovig™ for the prevention of migraine in patients experiencing four or more migraine days per month. The FDA has set a PDUFA target action date of May 17, 2018.

In January 2018, a phase 3b study met its primary endpoint and all secondary endpoints in patients with episodic migraine who had experienced two to four previous preventive treatment failures due to lack of efficacy or intolerable side effects.

Aranesp®

Aranesp® is a recombinant human protein agonist of the erythropoietin receptor. It is being investigated as a treatment for low risk myelodysplastic syndromes.

In October 2017, we announced that a phase 3 post-marketing requirement study to evaluate the safety and efficacy of Aranesp® in anemic patients with advanced non-small cell lung cancer receiving multi-cycle chemotherapy successfully met its primary endpoint of non-inferiority in overall survival compared to placebo, with no new safety findings.

BLINCYTO®

BLINCYTO® is an anti-CD19 x anti-CD3 (BiTE®) bispecific antibody construct.

A phase 2/3 study in patients with relapsed or refractory DLBCL is ongoing. In December 2017, we announced that the FDA accepted for priority review the sBLA for the treatment of minimal residual disease in patients with ALL. The PDUFA target action date is March 29, 2018.

In July 2017, we announced that the FDA approved the sBLA for BLINCYTO® to include overall survival data from the phase 3 TOWER study. The approval converts BLINCYTO®'s accelerated approval to a full approval. The approval expands the indication of BLINCYTO® for the treatment of relapsed or refractory B-cell precursor ALL in adults and children.

In February 2018, we announced that the CHMP of the EMA adopted a positive opinion recommending a label variation for BLINCYTO® to include overall survival data from the phase 3 TOWER study supporting the conversion of the conditional marketing authorization to a full marketing authorization in adult patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL.

ENBREL

ENBREL is a fusion protein that inhibits tumor necrosis factor.

Phase 3 studies to evaluate ENBREL as a monotherapy for psoriatic arthritis treatment and as a monotherapy in maintaining remission in rheumatoid arthritis are ongoing.

EVENITY™

EVENITY™ is a humanized monoclonal antibody that inhibits the action of sclerostin. It is being evaluated as a treatment for osteoporosis. EVENITY™ is being developed in collaboration with UCB.

In May 2017, we and UCB announced that the phase 3 ARCH study in postmenopausal women with osteoporosis met both primary endpoints and the key secondary endpoint. An imbalance in positively adjudicated cardiovascular serious adverse events was observed in the study as a new safety signal.

In July 2017, we and UCB announced that the FDA issued a Complete Response Letter for the BLA for EVENITY™ as a treatment for postmenopausal women with osteoporosis. The resubmission will include data from the phase 3 ARCH study and select data from the phase 3 BRIDGE study evaluating EVENITY™ in men with osteoporosis, in addition to the phase 3 FRAME study. We are currently evaluating all EVENITY™ data and will be working in close collaboration with the FDA.

In January 2018, we and UCB announced that the EMA accepted the MAA for EVENITY™ for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture.

IMLYGIC®

IMLYGIC® is an oncolytic immunotherapy derived from herpes simplex virus type 1.

A phase 1b/3 study to evaluate IMLYGIC® in combination with Merck & Company, Inc.'s (Merck's) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with mid- to late-stage metastatic melanoma is ongoing.

KYPROLIS®

KYPROLIS® is a proteasome inhibitor.

In July 2017, we announced positive results from the final analysis of the phase 3 ASPIRE study. The study met the key secondary endpoint of overall survival, demonstrating that KYPROLIS®, lenalidomide and dexamethasone reduced the risk of death by 21% over lenalidomide and dexamethasone alone. In December 2017, we submitted a sNDA to the FDA and a variation to the marketing authorization to the EMA to include the overall survival data from the ASPIRE study in the product label.

In October 2017, we announced top-line results of the phase 3 ARROW study, which showed KYPROLIS® administered once-weekly at the 70 mg/m^2 dose with dexamethasone allowed relapsed and refractory multiple myeloma patients to live 3.6 months longer without their disease worsening than KYPROLIS® administered twice-

weekly at the 27 mg/m^2 dose with dexamethasone. The overall safety profile of the once-weekly KYPROLIS® regimen was comparable to that of the twice-weekly regimen.

In January 2018, we announced that the CHMP of the EMA has adopted a positive opinion recommending a label variation for KYPROLIS® to include updated overall survival data from the phase 3 head-to-head ENDEAVOR study in patients with relapsed or refractory multiple myeloma. The ENDEAVOR study demonstrated that KYPROLIS® and dexamethasone reduced the risk of death by 21 percent, and increased overall survival by 7.6 months versus VELCADE® and dexamethasone.

A phase 3 study comparing carfilzomib, dexamethasone, and daratumumab to carfilzomib and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma is ongoing.

Omecamtiv mecarbil

Omecamtiv mecarbil is a small-molecule activator of cardiac myosin. It is being evaluated for the treatment of chronic heart failure. Omecamtiv mecarbil is being developed by Amgen in collaboration with Cytokinetics, Inc. and in collaboration with Servier for certain territories.

A phase 3 cardiovascular outcomes study for the treatment of chronic heart failure is ongoing.

Prolia®

Prolia® is a human monoclonal antibody that inhibits RANKL. It is being investigated for the treatment of glucocorticoid-induced osteoporosis.

In October 2017, we announced that the FDA accepted for review the sBLA for the treatment of patients with glucocorticoid-induced osteoporosis. The FDA has set a PDUFA target action date of May 28, 2018.

Tezepelumab (formerly AMG 157)

Tezepelumab is a human monoclonal antibody that inhibits the action of thymic stromal lymphopoietin. It is being evaluated as a treatment for asthma in an ongoing phase 3 study, as well as atopic dermatitis. Tezepelumab is being jointly developed in collaboration with AstraZeneca plc (AstraZeneca).

AMG 301

AMG 301 is a human monoclonal antibody that inhibits the pituitary adenylate cyclase-activating polypeptide type 1 (PAC1) receptor. It is being investigated for migraine prevention. AMG 301 is being jointly developed in collaboration with Novartis.

AMG 520 / CNP520

AMG 520 / CNP520 is a small molecule inhibitor of beta-site amyloid precursor protein-cleaving enzyme-1 (BACE). It is being evaluated for the prevention of Alzheimer's disease, with phase 3 studies ongoing. AMG 520 / CNP520 is being jointly developed in collaboration with Novartis.

AMG 557

AMG 557 is a human monoclonal antibody that inhibits the action of the ICOS ligand. It is being investigated as a treatment for primary Sjögren's syndrome. AMG 557 is being jointly developed in collaboration with AstraZeneca.

AMG 714

AMG 714 is a human monoclonal antibody that binds to Interleukin-15. It is being investigated for the treatment of celiac disease. In November 2017, Amgen reacquired the AMG 714 program from Celimmune LLC.

Amgen Development of Biosimilars

We continue to develop and commercialize biosimilar medicines. Our biosimilar product candidates are in varying stages of commercialization and clinical development as described in the following table:

Program	Reference product	Status
AMJEVITA™ / AMGEVITA™	adalimumab (HUMIRA®)	Approved by FDA and EC across all eligible indications of reference product
MVASI™*	bevacizumab (Avastin®)	Approved by FDA and EC across all eligible indications of reference product
ABP 710	infliximab (REMICADE®)	Phase 3 rheumatoid arthritis study ongoing
ABP 798*		Phase 3 rheumatoid arthritis study ongoing

	rituximab (Rituxan® / Mabthera®)	Phase 3 non-Hodgkin's lymphoma study ongoing
ABP 959	eculizumab (Soliris®)	Phase 1 completed
ABP 980*	trastuzumab (Herceptin®)	BLA submitted to FDA; MAA submitted to EMA

* Developed in collaboration with Allergan

Business Relationships

From time to time, we enter into business relationships, including joint ventures and collaborative arrangements, for the R&D, manufacture and/or commercialization of products and/or product candidates. In addition, we also acquire product and R&D technology rights and establish R&D collaborations with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. These arrangements generally provide for non-refundable, upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. The activities under these collaboration agreements are performed with no guarantee of either technological or commercial success, and each is unique in nature.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require counterparties to execute confidentiality agreements upon the commencement of the business relationship with us. However, others could either develop independently the same or similar information or unlawfully obtain access to our information.

Kirin-Amgen, Inc.

On October 30, 2017, we announced that we agreed to acquire the remaining 50% ownership interest of Kirin-Amgen, Inc. (K-A) from Kirin Holdings Company, Limited (Kirin). We completed the share acquisition during the first quarter of 2018, making K-A a wholly owned subsidiary of Amgen. Prior to the closing of the share acquisition, K-A was a 50-50 joint venture with Kirin. K-A develops and then licenses all product rights which have been transferred from Amgen and Kirin. See Part IV—Note 21, Subsequent event, to the Consolidated Financial Statements.

K-A has given us exclusive licenses to manufacture and market: (i) granulocyte colony-stimulating factor (G-CSF) and pegfilgrastim in the United States, Europe, Canada, Australia, New Zealand, all Central American, South American, Middle Eastern and African countries and certain countries in Asia; (ii) darbepoetin alfa and romiplostim in the United States, Europe, Canada, Australia, New Zealand, Mexico, all Central and South American countries and certain countries in Central Asia, Africa and the Middle East; and (iii) recombinant human erythropoietin in the United States. We currently market pegfilgrastim, G-CSF, darbepoetin alfa, recombinant human erythropoietin and romiplostim under the brand names Neulasta®, NEUPOGEN®/GRANULOKINE®, Aranesp®, EPOGEN® and Nplate®, respectively. Under these agreements, Amgen pays K-A royalties based on product sales. In addition, Amgen also receives payments from K-A for milestones earned and for conducting certain R&D activities on its behalf.

K-A has also given Kirin exclusive licenses to manufacture and market: (i) G-CSF and pegfilgrastim in Japan, Taiwan and South Korea; (ii) darbepoetin alfa, romiplostim and brodalumab in Japan, China, Taiwan, South Korea and in certain other countries and/or regions in Asia; and (iii) recombinant human erythropoietin in Japan. K-A also gave Kirin and Amgen co-exclusive licenses to manufacture and market G-CSF, pegfilgrastim and recombinant human erythropoietin in China, which Amgen subsequently assigned to Kirin, and as a result, Kirin now exclusively manufactures and markets G-CSF and recombinant human erythropoietin in China. Kirin markets G-CSF, pegfilgrastim, darbepoetin alfa, romiplostim, recombinant human erythropoietin and brodalumab under the brand names GRAN®/Grasin®, Peglasta®/Neulasta®/G-Lasta®, NESP®/Aranesp®, ROMIPLATE®, ESPO® and LUMICEF®, respectively. Under these agreements, Kirin pays K-A royalties based on product sales. In addition, Kirin also receives payments from K-A for conducting certain R&D activities on its behalf.

K-A has also given J&J exclusive licenses to manufacture and market recombinant human erythropoietin for all geographic areas of the world outside the United States, China and Japan. Under this agreement, J&J pays royalties to K-A based on product sales. See Part IV—Note 8, Related party transactions, to the Consolidated Financial Statements.

Novartis

In April 2017, we expanded our existing migraine collaboration with Novartis. In the United States, Amgen and Novartis will jointly develop and collaborate on the commercialization of Aimovig™. Amgen, as the principal, will recognize product sales of Aimovig™ in the United States, will share U.S. commercialization costs with Novartis and will pay Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig™ and other specified migraine programs. Novartis will pay Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories. Novartis will fund a portion of global R&D expenses. Novartis will also make payments to Amgen that could collectively amount to approximately $400 million if certain regulatory events occur and

commercial thresholds are achieved with respect to Aimovig™ in the United States. Amgen will manufacture and supply Aimovig™ worldwide.

Pfizer Inc.

The co-promotion term of our ENBREL collaboration agreement with Pfizer Inc. (Pfizer) in the United States and Canada expired on October 31, 2013. Under this agreement, we paid Pfizer a profit share until October 31, 2013, and residual royalties from November 1, 2013 to October 31, 2016, which were significantly less than the profit share payments. In 2015 and 2016, the residual royalty payments ranged from 11% to 10% of annual net ENBREL sales in the United States and Canada. Effective November 1, 2016, there are no further royalty payments.

UCB

We are in a collaboration with UCB for the development and commercialization of EVENITY™. In 2016, we amended the commercialization rights and responsibilities of the parties. Under the amended agreement, we have the rights to commercialize EVENITY™ for all indications in the United States, Japan and Hong Kong. UCB has the rights for Europe, China and Brazil. The rest of the countries have been allocated to Amgen. Generally, development costs and future worldwide commercialization profits and losses related to the collaboration after accounting for expenses are shared equally.

Bayer HealthCare Pharmaceuticals Inc.

We are in a collaboration with Bayer HealthCare Pharmaceuticals Inc. (Bayer) to jointly develop and commercialize Nexavar® (sorafenib). In 2015, we amended the terms of our collaboration agreement with Bayer, which terminated the co-promotion agreement in the United States, and transferred all U.S. operational responsibilities to Bayer, including commercial and medical affairs activities. Prior to the termination of the co-promotion agreement, we co-promoted Nexavar® with Bayer and shared equally in the profits in the United States. In lieu of this profit share, Bayer now pays us a royalty on U.S. sales of Nexavar® at a percentage rate in the high 30s. Outside of the United States, excluding Japan, Bayer manages all commercialization activities and incurs all of the sales and marketing expenditures and mutually agreed R&D expenses, and we reimburse Bayer for half of those expenditures. In all countries outside of the United States, except Japan, we receive 50% of net profits on sales of Nexavar® after deducting certain Bayer-related costs. The rights to develop and market Nexavar® in Japan are reserved to Bayer.

DaVita Inc.

In January 2017, we entered into a six-year supply agreement with DaVita Inc. (DaVita), which superseded the previously existing seven-year supply agreement that commenced in 2012. Pursuant to the 2017 agreement, we supply EPOGEN® and Aranesp® in amounts necessary to meet specified annual percentages of DaVita's and its affiliates' requirements for erythropoiesis-stimulating agents (ESAs) used in providing dialysis services in the United States and Puerto Rico. Such percentage varies during the term of the agreement, but in each year is at least 90%. The agreement expires in 2022. The agreement may be terminated by either party before expiration of its term in the event of certain breaches of the agreement by the other party.

Human Resources

As of December 31, 2017, Amgen had approximately 20,800 staff members. We consider our staff relations to be good.

Executive Officers of the Registrant

The executive officers of the Company as of February 7, 2018, are set forth below.

Mr. Robert A. Bradway, age 55, has served as a director of the Company since October 2011 and Chairman of the Board of Directors since 2013. Mr. Bradway has been the Company's President since 2010 and Chief Executive Officer since 2012. From 2010 to 2012, Mr. Bradway served as the Company's President and Chief Operating Officer. Mr. Bradway joined the Company in 2006 as Vice President, Operations Strategy and served as Executive Vice President and Chief Financial Officer from 2007 to 2010. Prior to joining the Company, he was a Managing Director at Morgan Stanley in London where, beginning in 2001, he had responsibility for the firm's banking department and corporate finance activities in Europe. Mr. Bradway has been a director of The Boeing Company, an aerospace company and manufacturer of commercial airplanes, defense, space and securities systems, since 2016. He has served on the board of trustees of the University of Southern California since 2014, and on the advisory board of the Leonard D. Schaeffer Center for Health Policy and Economics at that university since 2012. From 2011 to May 2017, Mr. Bradway was a director of Norfolk Southern Corporation, a transportation company.

Mr. Jonathan P. Graham, age 57, became Senior Vice President, General Counsel and Secretary in 2015. From 2006 to 2015, Mr. Graham was Senior Vice President and General Counsel at Danaher Corporation. From 2004 to 2006, Mr. Graham was Vice President, Litigation and Legal Policy at General Electric Company (GE). Prior to GE, Mr. Graham was a partner at Williams & Connolly LLP.

Dr. Sean E. Harper, age 55, became Executive Vice President, Research and Development in 2012. Dr. Harper joined the Company in 2002, and has held leadership roles in early development, medical sciences and global regulatory and safety. Dr. Harper served as Senior Vice President, Global Development and Corporate Chief Medical Officer from 2007 to 2012. Prior to joining the Company, Dr. Harper worked for five years at Merck Research Laboratories.

Mr. Anthony C. Hooper, age 63, became Executive Vice President, Global Commercial Operations in 2011. From 2010 to 2011, Mr. Hooper was Senior Vice President, Commercial Operations and President, U.S., Japan and Intercontinental of Bristol-Myers Squibb Company (BMS). From 2009 to 2010, Mr. Hooper was President, Americas of BMS. From 2004 to 2009, Mr. Hooper was President, U.S. Pharmaceuticals, Worldwide Pharmaceuticals Group, a division of BMS. Prior to this, Mr. Hooper held various senior leadership positions at BMS. Prior to joining BMS, Mr. Hooper was Assistant Vice President of Global Marketing for Wyeth Laboratories.

Ms. Lori A. Johnston, age 53, became Senior Vice President in 2016. From 2012 to 2016, Ms. Johnston was Executive Vice President and Chief Administrative Officer of Celanese Corporation. From 2006 to 2012, Ms. Johnston served in a series of progressive leadership roles at Amgen, with her last position being Vice President, Human Resources. Prior to joining the Company, Ms. Johnston held human resources and other positions at Dell Inc.

Mr. David W. Meline, age 60, became Executive Vice President and Chief Financial Officer in 2014. From 2011 to 2014, Mr. Meline served as Senior Vice President and Chief Financial Officer at 3M Company (3M). From 2008 to 2011, Mr. Meline served as Vice President, Corporate Controller and Chief Accounting Officer of 3M. Prior to 2008, Mr. Meline served in a variety of senior leadership roles for General Motors Company for over 20 years, with his last position being Vice President and Chief Financial Officer, North America. Mr. Meline has been a director of ABB Ltd., a global industrial technology company based in Switzerland, since 2016, serving as a member of the Finance, Audit and Compliance Committee. Mr. Meline was a director of TRW Automotive Holdings, Corp., a supplier of automotive systems, modules and components, from 2014 until its acquisition by ZF Friedrichshafen AG in 2015.

Ms. Cynthia M. Patton, age 56, became Senior Vice President and Chief Compliance Officer in 2012. Ms. Patton joined the Company in 2005. From 2005 to 2010, Ms. Patton was Associate General Counsel. From 2010 to 2012, Ms. Patton was Vice President, Law. Previously, Ms. Patton served as Senior Vice President, General Counsel and Secretary of SCAN Health Plan from 1999 to 2005.

Mr. David A. Piacquad, age 61, became Senior Vice President, Business Development in 2014. Mr. Piacquad joined the Company in 2010 and, until 2014, served as Vice President, Strategy and Corporate Development. From 2014 to 2014, Mr. Piacquad served as Vice President, Business Development. Prior to joining the Company, from 2009 to 2010, Mr. Piacquad was Principal of David A. Piacquad Consulting LLC. From 2006 to 2009, Mr. Piacquad served as Senior Vice President, Business Development and Licensing for Schering-Plough Corporation. Prior to Schering-Plough, Mr. Piacquad served in a series of leadership roles in finance and business development at J&J, with his last position being Vice President, Ventures and Business Development.

Mr. Esteban Santos, age 50, became Executive Vice President, Operations in 2016. Mr. Santos joined the Company in 2007 as Executive Director, Manufacturing Technologies. From 2008 to 2013, Mr. Santos held a number of Vice President roles at the Company in engineering, manufacturing, site operations and drug product. From 2013 to 2016, Mr. Santos was Senior Vice President, Manufacturing. Prior to joining the Company, Mr. Santos served as Site General Manager for J&J's Cordis operation in Puerto Rico. Prior to J&J, Mr. Santos held several management positions in GE's industrial and transportation businesses.

Geographic Area Financial Information

For financial information concerning the geographic areas in which we operate, see Part IV—Note 19, Segment information—Geographic information, to the Consolidated Financial Statements.

Investor Information

Financial and other information about us is available on our website at www.amgen.com. We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission (SEC). In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected, without charge, at the SEC's public reference room at 100 F Street NE, Washington, DC 20549, or at the SEC's website at www.sec.gov. (These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.) Information related to the operation of the SEC's public reference room may be obtained by calling the SEC at 800-SEC-0330.

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. The statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability.

Sales of our products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers continue to pursue aggressive initiatives to contain costs and manage drug utilization and are increasingly focused on the effectiveness, benefits and costs of similar treatments, which could result in lower reimbursement rates for our products or narrower populations for whom our products will be reimbursed by payers. Intense public scrutiny of the price of drugs and other healthcare costs continues and greater focus on pricing and price increases may limit our ability to set or increase the price of our products based on their value, which could have a material adverse effect on our product sales, business and results of operations.

A substantial portion of our U.S. business relies on reimbursement from U.S. federal government healthcare programs and commercial insurance plans regulated by the U.S. federal and state governments. See Item 1. Business —Reimbursement. Changes to U.S. federal reimbursement policy may come through legislative and/or administrative actions. Discussions continue around a number of potential legislative changes that could affect the reimbursement and/or pricing of our products, including proposals to allow the U.S. federal government to directly negotiate drug prices with pharmaceutical manufacturers and to require manufacturers to pay higher rebates in the Medicare Part D setting. Legislation has been introduced into the U.S. Congress for other proposals, including legislation designed to overhaul provisions of the ACA as well as to enable commercial-level re-importation of prescription medications from Canada or other countries. State government actions or ballot initiatives can also affect how our products are covered and reimbursed or create additional pressure on how our products are priced. Some states have adopted, and many other states have discussed and debated and are considering, new pricing legislation, including state proposals designed to require biopharmaceutical manufacturers to publicly report proprietary pricing information, limit price increases or to place a maximum price ceiling, or cap, on pharmaceutical products. For example, in October 2017, California's governor signed into law a new drug pricing transparency bill that requires pharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. Existing and proposed pricing legislation could lead to the introduction and passage of additional bills or ballot initiatives in other states. While we are unable to predict if additional changes may ultimately be enacted, to the extent that these or other changes affect how our products are priced, paid for and reimbursed by government and private payers in the United States our business could be

adversely impacted. Changes in U.S. federal reimbursement policy may also arise as a result of regulations or demonstration projects implemented by the CMS, the federal agency responsible for administering Medicare, Medicaid and the Health Insurance Marketplaces. CMS has substantial power to quickly implement policy changes that can significantly affect how our products are covered and reimbursed. Further, CMS is undertaking other projects to test care models, such as the CMS Oncology Care Model that provides participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare

costs without negatively impacting the efficacy of care. We believe the Oncology Care Model has impacted utilization of certain of our oncology products by participating physician practices and may continue to do so in the future. CMS has also solicited suggestions regarding other potential care models. In addition, the timing of reimbursement policy decisions can affect our business. Legislative or regulatory changes in the United States or other federal or state government initiatives that decrease the coverage or reimbursement available for our products, require that we pay increased rebates, limit our ability to offer co-pay payment assistance to commercial patients, limit the pricing of pharmaceutical products or reduce the use of our U.S. products could have a material adverse effect on our business and results of operations.

Payers, including healthcare insurers, PBMs and group purchasing organizations, increasingly seek ways to reduce their costs. Many payers continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients. Such measures include more limited benefit plan designs, higher patient co-pay or co-insurance obligations and limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs.) Payers also increasingly seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage. Payers also control costs by imposing restrictions on access to or usage of our products, such as by requiring prior authorizations or step therapy, and may choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. For example, some providers do not complete the burdensome administrative process required to demonstrate or document that the patients for whom Repatha® has been prescribed meet the payers' utilization management criteria and, as a result, patients do not gain access to Repatha® treatment. Further, other patients may obtain coverage for Repatha® but abandon their prescriptions rather than pay their co-pay payment. Significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. Further consolidation among insurers, PBMs and other payers, including through integrated delivery systems, would increase the negotiating leverage such entities have over us and other drug manufacturers. Ultimately, further discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products.

Outside the United States, we expect countries will continue to take aggressive actions to reduce their healthcare expenditures. See Item 1. Business—Reimbursement. For example, international reference pricing (IRP) is widely used by a large number of countries to control costs based on an external benchmark of a product's price in other countries. IRP policies can quickly and frequently change and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. Any deterioration in the coverage and reimbursement available for our products or in the timeliness or certainty of payment by payers to physicians and other providers could negatively impact the ability or willingness of healthcare providers to prescribe our products for their patients or could otherwise negatively affect the use of our products or the prices we receive for them. Such changes could have a material adverse effect on our product sales, business and results of operations.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products. In the United States, pricing data that we submit to the U.S. government impacts the payment rates for providers, rebates we pay, and discounts we are required to provide under Medicare, Medicaid and other government drug programs. Government price reporting regulations are complex and may require a manufacturer to update certain previously submitted data. Our price reporting data calculations are reviewed monthly and quarterly, and based on such reviews we have on occasion restated previously reported pricing data to reflect changes in calculation methodology, reasonable assumptions and/or underlying data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data, we also may be required to pay additional rebates and provide additional discounts.

We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future.

We currently face competition from biosimilars in both Europe and the United States, and we expect to face increasing biosimilar and/or generics competition this year and beyond. Expiration or successful challenge of applicable patent rights or expiration of an applicable data exclusivity period would accelerate such competition, and we expect to face more litigation regarding the validity and/or scope of our patents. Our products may also experience greater competition from lower-cost biosimilars or generics that come to market when branded products that compete with our products lose their own patent protection. To the extent that governments adopt more

permissive approval frameworks and competitors are able to obtain broader or expedited marketing approval for biosimilars and generics, the rate of increased competition for our products could accelerate.

In the EU, biosimilars are evaluated and authorized pursuant to a set of general and product class-specific guidelines. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU countries have adopted and others are attempting to adopt biosimilar uptake measures such as requiring physician prescribing quotas or promoting switching or pharmacy substitution of biosimilars for the corresponding reference products, and other countries may adopt similar measures. Some EU countries impose automatic price reductions upon market entry of one or more biosimilar competitors.

In the United States, the ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. See Item 1. Business—Government Regulation—Regulation in the United States—Approval of Biosimilars. The first biosimilar entrant into the U.S. market, Sandoz's Zarxio®, is a biosimilar version of NEUPOGEN®, and was launched in the United States in 2015. Since then, the FDA has approved additional biosimilars, including a biosimilar version of ENBREL. In addition, a growing number of companies have announced that they are in varying stages of development of biosimilar versions of existing biotechnology products, including biosimilars that would compete with our products. Companies pursuing development of biosimilar versions of our products have challenged and may continue to challenge our patents well in advance of the expiration of our material patents. For information related to our biosimilars patent litigation, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements. See *Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in present and future intellectual property litigation.* The U.S. pathway includes the option for biosimilar products that meet certain criteria to be approved as interchangeable with their reference products. Some companies currently developing biosimilars may seek to register their products as interchangeable biologics, which could make it easier for pharmacists to substitute those biosimilars for our products or could encourage prescribers who are inclined to select the interchangeable biosimilar over our innovative products. In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law's provisions regarding which new products receive data exclusivity, which could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, public, legislative, and FDA efforts to promote price competition through easier generic entry. While we are unable to predict the precise impact of biosimilars on our products, we are currently facing and expect to face greater competition in the United States, Europe and elsewhere this year and beyond as a result of biosimilar and generic competition and downward pressure on our product prices and sales. This competition has had and could increasingly have a material adverse effect on our business and results of operations.

Our products face substantial competition.

We operate in a highly competitive environment. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We expect that our products will compete with new drugs currently in development, drugs currently approved for other indications that may later be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. Large pharmaceutical companies and generics manufacturers of pharmaceutical products are expanding into the biotechnology field, and some pharmaceutical companies and generics manufacturers have formed partnerships to pursue biosimilars. In addition, some of our competitors may have technical, competitive or other advantages over us for the development of technologies and processes or greater experience in particular therapeutic areas, and consolidation among pharmaceutical and biotechnology companies can enhance such advantages. These advantages may make it difficult for us to compete with them to successfully discover, develop and market new products and for our current products to compete with new products or new product indications they may bring to market. As a result, our products may compete against products that have lower prices, equivalent or superior performance, better safety profiles, easier administration, earlier market availability or other competitive features. If we are unable to compete effectively, this could reduce sales, which could have a material adverse effect on our business and results of operations.

Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in present and future intellectual property litigation.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. Challenges to patents may come from potential competitors or from parties other than those who seek to market a potentially-infringing product. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We have been in the past, and are currently and expect to be in the future, involved in patent litigation. These matters have included and may in the future include litigation with manufacturers of products that purport to be biosimilars of certain of our products for patent infringement and for failure to comply with certain provisions of the Biologics Price Competition and Innovation Act, including the requirement to provide 180 days' notice in advance of commercial marketing. A determination made by a court,

agency or tribunal concerning infringement, validity, enforceability, injunctive or economic remedy, or the right to patent protection, for example, are typically subject to appellate or administrative review. Upon review, such initial determinations may be afforded little or no deference by the reviewing tribunal and may be affirmed, reversed, or made the subject of reconsideration through further proceedings. A patent dispute or litigation may not discourage a potential violator from bringing the allegedly-infringing product to market prior to a final resolution of the dispute or litigation. The period from inception until resolution of a patent dispute or litigation is subject to the availability and schedule of the court, agency or tribunal before which the dispute or litigation is pending. We may be subject to competition during this

period and may not be able to recover fully from the losses, damages, and harms we incur from infringement by the competitor product even if we prevail. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities, be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Further, under the Hatch-Waxman Act, our products approved by the FDA under the FDCA may be the subject of patent litigation with generics competitors before expiry of the five-year period of data exclusivity provided for under the Hatch-Waxman Act and prior to the expiration of the patents listed for the product. Likewise, our innovative biologic products may be the subject of patent litigation prior to the expiration of our patents and, with respect to competitors seeking approval as a biosimilar or interchangeable version of our products, prior to the 12-year exclusivity period provided under the ACA. In addition, we may face additional patent litigation involving claims that the biosimilar product candidates we are working to develop infringe the patents of other companies that manufacture, market or sell the applicable reference products. While we may attempt to challenge such patents, our efforts may be unsuccessful. For information related to our patent litigation with manufacturers of proposed generic and biosimilar versions of our products, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

Certain of the existing patents on our products have recently expired. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents. As our patents expire, competitors are able to legally produce and market similar products or technologies, including biosimilars, which may have a material adverse effect on our product sales, business and results of operations. In addition, competitors may be able to invalidate, design around or otherwise circumvent our patents and sell competing products.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. However, professional societies, practice management groups, insurance carriers, physicians groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities. Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies, and a growing number of organizations are providing assessments of the value and pricing of pharmaceutical products. These assessments may come from private organizations, such as the Institute for Clinical and Economic Review (ICER), which publish their findings and offer recommendations relating to the products' reimbursement by government and private payers. In addition, government HTA organizations, such as the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom and the Canadian Agency for Drugs and Technologies in Health, make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service impact of new, emerging and existing medicines and treatments. Such HTA organizations may recommend reimbursement for our product for a narrower indication than was approved by applicable regulatory agencies, or may recommend against reimbursement entirely. Such recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could have a material adverse effect on our product sales, business and results of operations. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price of our common stock.

Our current products and products in development cannot be sold without regulatory approval.

Our business is subject to extensive regulation by numerous state and federal government authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in foreign countries to obtain approval from regulatory authorities before we manufacture, market and sell our products. Once our products are approved, the FDA and other U.S. and foreign regulatory agencies have substantial authority to require additional testing and reporting, perform inspections, change product labeling or mandate withdrawals of our products. Failure to comply with applicable regulatory requirements may subject us to administrative and/or judicially imposed sanctions or monetary penalties as well as reputational and other harms. The sanctions could include the FDA's or foreign regulatory authorities' refusals to approve pending applications, delays in obtaining or withdrawals of approvals, delays or suspensions of clinical trials, warning letters, product recalls or seizures, total or partial suspensions of our operations, injunctions, fines, civil penalties and/or criminal prosecutions.

Obtaining and maintaining regulatory approval have been, and will continue to be, increasingly difficult, time-consuming and costly. Legislative bodies or regulatory agencies could enact new laws or regulations, change existing laws or regulations, or change their interpretations of laws or regulations at any time, which could affect our ability

to obtain or maintain approval of our products or product candidates. The rate and degree of change in existing laws and regulations and regulatory expectations have accelerated in established markets, and regulatory expectations continue to evolve in emerging markets. We are unable to predict whether and when any further changes to laws or regulatory policies affecting our business could occur, such as changes to

regulations governing manufacturer communications concerning drug products and drug product candidates, and whether such changes could have a material adverse effect on our business and results of operations.

Regulatory authorities may also question the sufficiency for approval of the endpoints we select for our clinical trials. A number of our products and product candidates have been evaluated in clinical trials using surrogate endpoints that measure an effect that is known to correlate with an ultimate clinical endpoint. For example, a therapeutic oncology product candidate may be evaluated for its ability to extend the length of time during and after the treatment that a patient lives without the disease worsening, measured by progression-free survival (PFS). Demonstrating that the product candidate produces a statistically significant improvement in PFS does not necessarily mean that the product candidate will show a statistically significant improvement in overall survival, or the time that the patients remain alive. In the cardiovascular setting, a heart disease therapeutic candidate may be evaluated for its ability to reduce LDL-C levels, as elevated LDL-C level has been a surrogate endpoint for cardiovascular events such as death, heart attack and stroke. The use of surrogate endpoints such as PFS and LDL-C reduction, in the absence of other measures of clinical benefit, may not be sufficient for broad usage or approval even when such results are statistically significant. Regulatory authorities could also add new requirements, such as the completion of enrollment in a confirmatory study or the completion of an outcomes study or a meaningful portion of an outcomes study, as conditions for obtaining approval or obtaining an indication. For example, our initial FDA application for Repatha® sought approval for a broader patient population based on data demonstrating that Repatha® reduced LDL-C levels. However, the FDA initially approved Repatha® in 2015 only for a subset of those patients, citing among other things the absence of positive outcomes data showing that Repatha® prevents cardiovascular events. In December 2017, the FDA granted broader approval of Repatha® to reduce the risk of certain cardiovascular events, and also to be used, alone or in combination with other lipid-lowering therapies, for the treatment of adults with primary hyperlipidemia to reduce LDL-C, only after our large phase 3 outcomes study evaluating the ability of Repatha® to prevent cardiovascular events met its primary composite endpoint and key secondary composite endpoint. See Item 1. Business—Significant Developments. There may also be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to other existing treatment options can be shown. The imposition of additional requirements or our inability to meet them in a timely fashion or at all may delay our clinical development and regulatory filing efforts, delay or prevent us from obtaining regulatory approval for new product candidates or new indications for existing products, or prevent us from maintaining our current labels.

Some of our products have been approved by U.S. and foreign regulatory authorities on a conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, BLINCYTO® received conditional marketing authorization for the treatment of patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL from the EC in November 2015, with full authorization conditioned on demonstrating clinical effectiveness and safety in clinical practice and in a subsequent clinical trial. Regulatory authorities are placing greater focus on monitoring products originally approved on an accelerated or conditional basis and on whether the sponsors of such products have met the conditions of the accelerated or conditional approvals. If we are unable to fulfill the regulators' requirements that were conditions of a product's accelerated or conditional approval and/or if regulators re-evaluate the data or risk-benefit profile of our product, the conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change the product's labeled indications or even withdraw the product from the market.

Safety problems or signals can arise as our products and product candidates are evaluated in clinical trials, including investigator sponsored studies, or as our marketed products are used in clinical practice. We are required to continuously collect and assess adverse events reported to us and to communicate to regulatory agencies these adverse events and safety signals regarding our products. Regulatory agencies periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. In 2012, pharmacovigilance legislation became effective in the EU that enhanced the authority of European regulators to require companies to conduct additional post-approval clinical efficacy and safety studies and increased the requirements on sponsor companies to analyze and evaluate the risk-benefit profiles of their products. Similarly, for our products with approved REMS (see Item 1. Business—Government Regulation—Post-approval Phase), we are required to submit periodic assessment reports to the FDA to demonstrate that the goals of the REMS are being met. REMS and other risk management programs are designed to ensure that a drug's benefits outweigh the risks, and vary in the elements they contain. If the FDA is not satisfied with the results of the periodic assessment reports we submit for any of our REMS, the FDA may also modify our REMS or take other regulatory actions, such as implementing revised or restrictive labeling. The drug delivery devices approved for use in combination with our products are also subject to regulatory oversight and review for safety and malfunctions. If regulatory agencies determine that we or other parties (including our clinical trial investigators, those operating our patient support programs or licensees of our products) have not complied with the applicable reporting, other pharmacovigilance or other safety or quality assessment requirements,

we may become subject to additional inspections, warning letters or other enforcement actions, including fines, marketing authorization withdrawal and other penalties. Our product candidates and marketed products can also be affected by safety problems or signals occurring with respect to products that are similar to ours and that implicate an entire class of products. Further, as a result of clinical trials, including sub-analyses or meta-analyses of earlier clinical trials (a meta-analysis

involves the use of various statistical methods to combine results from previous separate but related studies) performed by us or others, concerns may arise about the sufficiency of the data or studies underlying a product's approved label. Such actual or perceived safety problems or concerns can lead to:

- revised or restrictive labeling for our products, or the potential for restrictive labeling that may result in our decision not to commercialize a product candidate;
- requirement of risk management activities or other regulatory agency compliance actions related to the promotion and sale of our products;
- mandated post-marketing commitments or pharmacovigilance programs for our approved products;
- product recalls of our approved products;
- revocation of approval for our products from the market completely, or within particular therapeutic areas or patient types;
- increased timelines or delays in being approved by the FDA or other regulatory bodies; and/or
- fewer treatments or product candidates being approved by regulatory bodies.

For example, since 2006, when adverse safety results involving ESAs were observed, ESAs continue to be the subject of ongoing review and scrutiny. Reviews by regulatory authorities of the risk-benefit profile of ESAs have resulted in, and may continue to result in, changes to ESA labeling and usage in both the oncology and nephrology clinical settings.

In addition to our innovative products, we are working to develop and commercialize biosimilar versions of a number of products currently manufactured, marketed and sold by other pharmaceutical companies. In some markets, there is not yet a legislative or regulatory pathway for the approval of biosimilars. In the United States, the ACA provided for such a pathway; while the FDA continues to implement it, questions remain as to the evidence needed to demonstrate biosimilarity or interchangeability for specific products and what information can be included in biosimilar labeling. See *We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future.* Delays or uncertainties in the development of such pathways could result in delays or difficulties in getting our biosimilar products approved by regulatory authorities, subject us to unanticipated development costs or otherwise reduce the value of the investments we have made in the biosimilars area. Further, we cannot predict whether any repeal or reform of the ACA would affect the biosimilar pathway or have a material adverse effect on our development of biosimilars. In addition, if we are unable to bring our biosimilar products to market on a timely basis, and secure "first-to-market" positions, our future biosimilar sales and results of operations could be materially and adversely affected.

We may not be able to develop commercial products despite significant investments in R&D.

Amgen invests heavily in R&D. Successful product development in the biotechnology industry is highly uncertain, and very few R&D projects produce commercial products. Product candidates, including biosimilar product candidates, or new indications for existing products (collectively, product candidates) that appear promising in the early phases of development may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results, for reasons that could include changes in the standard of care of medicine;
- the product candidate was not effective or not more effective than currently available therapies in treating a specified condition or illness;
- the product candidate was not cost effective in light of existing therapeutics;
- the product candidate had harmful side effects in animals or humans;

- the necessary regulatory bodies, such as the FDA or EMA, did not approve the product candidate for an intended use;
- the product candidate was not economical for us to manufacture and commercialize;
- the biosimilar product candidate failed to demonstrate the requisite biosimilarity to the applicable reference product, or was otherwise determined by a regulatory authority to not meet applicable standards for approval;
- other parties had or may have had proprietary rights relating to our product candidate, such as patent rights, and did not let us sell it on reasonable terms, or at all;
- we and certain of our licensees, partners, contracted organizations or independent investigators may have failed to effectively conduct clinical development or clinical manufacturing activities; and
- the pathway to regulatory approval or reimbursement for product candidates was uncertain or not well-defined.

A number of our product candidates have failed or been discontinued at various stages in the product development process. For example, in May 2015, we terminated our participation in the co-development and commercialization of brodalumab with AstraZeneca. The decision was based on events of suicidal ideation and behavior in the brodalumab program, which we believed likely would necessitate restrictive labeling that would limit the appropriate patient population. Inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product for any of the reasons discussed could potentially have a negative impact on our product sales and earnings and could result in a significant impairment of in-process research and development (IPR&D) or other intangible assets.

We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.

Before we sell any products, we must conduct clinical trials to demonstrate that our product candidates are safe and effective for use in humans. The results of those clinical trials are used as the basis to obtain approval from regulatory authorities such as the FDA and EMA. See *Our current products and products in development cannot be sold without regulatory approval*. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims. The length of time, number of trial sites and number of patients required for clinical trials vary substantially, and we may spend several years and incur substantial expense in completing certain clinical trials. In addition, we may have difficulty finding a sufficient number of clinical trial sites and patients to participate in our clinical trials, particularly if competitors are conducting clinical trials in similar patient populations. Patients may withdraw from clinical trials at any time, and privacy laws and/or other restrictions in certain countries may restrict the ability of clinical trial investigators to conduct further follow-up on such patients, which may adversely affect the interpretation of study results. Delays and complications in planned clinical trials can result in increased development costs, associated delays in regulatory approvals and in product candidates reaching the market and revisions to existing product labels.

Further, to increase the number of patients available for enrollment in our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of locations where our experience conducting clinical trials is more limited, including Russia, India, China, South Korea, the Philippines, Singapore and some Central and South American countries, either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to understand the unique regulatory environments of individual countries. Further, we must ensure the timely production, distribution and delivery of the clinical supply of our product candidates to numerous and varied clinical trial sites. If we fail to adequately manage the design, execution and diverse regulatory aspects of our large and complex clinical trials or to manage the production or distribution of our clinical supply, corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates or could lose our ability to market existing products in certain therapeutic areas or altogether. If we are unable to market and sell our products or product candidates or to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations could be materially and adversely affected.

We rely on independent third-party clinical investigators to recruit patients and conduct clinical trials on our behalf in accordance with applicable study protocols, laws and regulations. Further, we rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations. In some circumstances, we enter into co-development arrangements with other pharmaceutical and medical devices companies that provide for the other company to conduct certain clinical trials for the product we are co-developing. We also may acquire companies that have past or ongoing clinical trials or rights to products or product candidates for which clinical trials have been or are being conducted. These trials may not have been conducted to the same standards as ours; however, once an acquisition has been completed we assume responsibility for the conduct of these trials, including any potential risks and liabilities associated with the past and prospective conduct of those trials. If regulatory authorities determine that we or others, including our licensees or co-development partners, or the independent investigators or vendors selected by us, our co-development partners or by a company we have acquired or from which we have acquired rights to a product or product candidate, have not complied with regulations applicable to the clinical trials, those authorities may refuse or reject some or all of the clinical trial data or take other actions that could negatively impact our ability to obtain or maintain marketing approval of the product or indication. If we were unable to market and sell our products or product candidates, our business and results of operations could be materially and adversely affected.

In addition, some of our clinical trials utilize drugs manufactured and marketed by other pharmaceutical companies. These drugs may be administered in clinical trials in combination with one of our products or product candidates or in a head-to-head study comparing the products' or product candidates' relative efficacy and safety. In the event that any of these vendors or pharmaceutical companies have unforeseen issues that negatively impact the quality of their work product or create a shortage of supply, or if we are otherwise unable to obtain an adequate

supply of these other drugs, our ability to complete our applicable clinical trials and/or evaluate clinical results may also be negatively impacted. As a result, such quality or supply problems could adversely affect our ability to timely file for, gain or maintain regulatory approvals worldwide.

Clinical trials must be designed based on the current standard of medical care. However, in certain diseases, such as cancer, the standard of care is evolving rapidly. In such diseases, the duration of time needed to complete certain clinical trials may result

in the design of such clinical trials being based on standards of medical care that are no longer the current standards by the time such trials are completed, limiting the utility and application of such trials. We may not obtain favorable clinical trial results and therefore may not be able to obtain regulatory approval for new product candidates or new indications for existing products and/or maintain our current product labels. Participants in clinical trials of our products and product candidates may also suffer adverse medical events or side effects that could, among other factors, delay or terminate clinical trial programs and/or require additional or longer trials to gain approval.

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a risk management plan for our product or for approval of a new indication. For example, in connection with the June 2011 ESA label changes, we agreed to and conducted additional clinical trials examining the use of ESAs in CKD. Additional clinical trials we initiate, including those required by the FDA, could result in substantial additional expense and the outcomes could result in further label restrictions or the loss of regulatory approval for an approved indication, each of which could have a material adverse effect on our business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our products, our business and results of operations.

Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.

Many of our products and product candidates may be used in combination with a drug delivery device, such as an injector or other delivery system. For example, Neulasta® is available as part of the Neulasta® Onpro® kit, and we recently launched the AutoTouch™ reusable auto-injector to be used with Enbrel Mini™ single-dose prefilled cartridges. In addition, some of our product candidates may also be used in combination with a companion diagnostic device. Our product candidates or expanded indications of our products used with such devices may not be approved or may be substantially delayed in receiving regulatory approval if such devices do not also gain or maintain regulatory approval or clearance. When approval of the product and device is sought under a single marketing drug application, the increased complexity of the review process may delay receipt of regulatory approval. In addition, some of these devices may be provided by single-source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or clearance by the applicable regulatory agencies. We are also dependent on those third-party companies continuing to meet applicable regulatory or other requirements. Failure to successfully develop or supply the devices, delays in or failures of the Amgen or third-party studies, or failure of us or the third-party companies to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs; delays in, or failure to obtain, regulatory approval; and/or associated delays in a product candidate reaching the market or in the addition of new indications for existing products. We are also required to collect and assess user complaints, adverse events, and malfunctions regarding our devices, and actual or perceived safety problems or concerns with a device used with our product can lead to regulatory actions and impacts to our products. See *Our current products and products in development cannot be sold without regulatory approval.* Additionally, regulatory agencies conduct routine monitoring and conduct inspections to identify and evaluate potential issues with our devices. For example, in 2017 the FDA reported on its adverse event reporting system that it is evaluating our Neulasta® Onpro® kit. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop, supply, or gain or maintain approval for these devices could adversely affect sales of the related, approved products.

The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability.

We are subject to income and other taxes in the United States and other jurisdictions in which we do business. As a result, our provision for income taxes is derived from a combination of applicable tax rates in the various places we operate. Significant judgment is required for determining our provision for income tax.

Our tax returns are routinely examined by tax authorities in the United States and other jurisdictions in which we do business, and a number of audits are currently underway. Tax authorities are becoming more aggressive in their audits and are particularly focused on the allocations of income and expense among tax jurisdictions. As previously disclosed, we received a Revenue Agent Report (RAR) from the Internal Revenue Service (IRS) for the years 2010, 2011, and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. On November 29, 2017, we received a modified RAR that revised their calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution through the IRS administrative appeals process, which we believe will likely not be concluded within the next 12 months. Final resolution of the IRS audit could have a material impact on our results of operations and cash flows if not resolved favorably. We believe our

accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. See Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred

tax assets and liabilities, and changes in applicable tax laws, regulations or administrative interpretations thereof. We incurred a net estimated tax expense of $6.1 billion due to the repatriation tax on accumulated foreign earnings and the remeasurement of certain net deferred and other tax liabilities as a result of the 2017 Tax Act. In computing our expense, we are allowed under new SEC accounting guidance to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We consider a number of key estimates we have made with respect to the 2017 Tax Act to be incomplete due to our continuing analysis of final year-end data and tax positions. Our continuing analysis (which will include evaluation of future U.S. Treasury regulations, accounting interpretations or other developments relating to the 2017 Tax Act) could affect the measurement of these balances and give rise to new deferred tax assets and liabilities. See Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Income taxes.

We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and substantially all of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.

We currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and substantially all of our clinical manufacturing activities at our facility in Thousand Oaks, California. The global supply of our products and product candidates for commercial sales and for use in our clinical trials is significantly dependent on the uninterrupted and efficient operation of these facilities. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales*.

In late September 2017, Hurricane Maria made landfall on the island of Puerto Rico. The hurricane destroyed residential and commercial buildings, agriculture, communications networks and most of Puerto Rico's electric grid. The critical manufacturing areas of our commercial manufacturing facility were not significantly impacted by the storm, and we have now resumed our full manufacturing operations. The restoration of electrical service on the island has been a slow process. As a result, our facility operated with electrical power from back-up diesel-powered generators through the end of 2017 and we received regular deliveries of diesel fuel under pre-arranged contracts. In January 2018, we reconnected to the Puerto Rico electric grid and began operating without the back-up generators. However, power has not been restored to the entire island, and it is possible that the electric grid may not remain stable and we may be required to resume use of our diesel generators. In addition, supplies of medical-grade oxygen and nitrogen used in biopharmaceutical manufacturing operations are limited on the island, and we have arranged deliveries of both gases from the U.S. mainland and other countries. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales*.

While nearly all of our staff have returned to work, some of them or their families may now or in the future be without housing, access to food and clean water, electricity, healthcare, sanitation, communications services, childcare, transportation or other essentials, and for these or other reasons some of our staff may be forced or elect to temporarily or permanently relocate elsewhere on or off the island. A substantial disruption in our ability to operate our Puerto Rico manufacturing facility (whether due to problems with the facility itself, the infrastructure and services available on the island, the unavailability of raw materials or supplies from vendors, the unavailability of key staff or otherwise) or get supplies and manufactured products transported to and from that location could materially and adversely affect our ability to supply our products and affect our product sales. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales*.

The impact of Hurricane Maria is certain to place greater stress on the island's already challenged economy. Since June 2015, when the Governor of Puerto Rico announced that the government (including certain government entities) was unable to pay its roughly $72 billion in debt, the government's liquidity position has continued to deteriorate and public reports indicate that the Puerto Rico government is not making certain payments with respect to its obligations. On June 30, 2016, President Obama signed into law the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA) to provide a mechanism for Puerto Rico to restructure its debt, achieve fiscal responsibility and gain access to capital markets. PROMESA established a federal Financial Oversight and Management Board (Oversight Board) to provide fiscal oversight through the development and approval of fiscal plans and budgets for Puerto Rico and to assist in the debt restructuring. In May 2017, after negotiations with creditors were unsuccessful and an automatic stay of creditor actions expired, the Oversight Board approved and certified the filing in the U.S. District Court for the District of Puerto Rico of a voluntary petition under Title III of PROMESA for the government of Puerto Rico, following thereafter with similar filings for certain Puerto Rico government entities. Title III of PROMESA provides Puerto Rico with a judicial process for restructuring its debt similar to, but not identical to, Chapter 9 of the U.S. Bankruptcy Code. Given the severe conditions in Puerto Rico after Hurricane Maria, it is expected that resolution of Puerto Rico's outstanding debt situation through the PROMESA judicial process will be delayed pending recovery efforts. Additionally, in January 2017, the Puerto Rico

government enacted the Puerto Rico Fiscal Emergency and Fiscal Responsibility Act, which, among other things, declared a state of financial emergency in Puerto Rico and authorized the Governor to designate certain services as essential services, and other services as non-essential in order to prioritize the use of available resources to satisfy Puerto Rico's obligations. The Puerto Rico government has continued to extend the emergency period. In June 2017, the Oversight Board certified the Puerto Rico government's budget for fiscal year 2018. In January 2018, the Puerto Rico government proposed a revised fiscal plan. The revised fiscal plan

is subject to approval by the Oversight Board and calls for delayed and reduced payments to creditors and assumes U.S. federal disaster assistance of $35 billion.

The Puerto Rico government is continuing to seek assistance from the U.S. government for disaster relief related to Hurricane Maria. In October 2017, the U.S. Congress approved a supplemental appropriation for disaster relief whereby Puerto Rico could receive a loan of up to approximately $5 billion to be used by the Puerto Rico government to provide essential services. U.S. and Puerto Rico officials are currently negotiating the terms and conditions of disaster relief loans that may be granted to Puerto Rico. In November 2017, the Governor of Puerto Rico submitted an additional request for federal disaster assistance to restore housing and rebuild a resilient power grid. It is not certain whether and what amounts will be appropriated by the U.S. Congress to assist in the hurricane recovery. In addition, the recently enacted U.S. tax reform legislation will no longer permit deferral of U.S. taxation on Puerto Rico earnings of U.S. companies (or their foreign subsidiaries), although these earnings generally will be taxed in the United States at a reduced 10.5% rate. Given Puerto Rico's challenged economy and hurricane recovery needs, it may be difficult for Puerto Rico to sustain or grow its manufacturing base due to competition from other foreign locations subject to a similar level of U.S. taxation, or U.S. locations due to the reduction in the U.S. corporate tax rate from 35% to 21%. The manufacturing sector currently contributes more than 45% of Puerto Rico's gross domestic product, and U.S. companies with Puerto Rico operations contribute more than 33% of Puerto Rico's revenue base.

While PROMESA and the actions above continue to be important factors in moving Puerto Rico toward economic stability, there is still a risk that Puerto Rico's ongoing economic challenges, the effects of Hurricane Maria and the potential impact of the 2017 Tax Act could negatively affect the territorial government's provision of utilities or other services in Puerto Rico that we use in the operation of our business, create the potential for increased taxes or fees to operate in Puerto Rico, result in a migration of workers from Puerto Rico to the mainland United States, and/or make it more expensive or difficult for us to operate in Puerto Rico, which could materially and adversely affect our ability to supply our products and affect our product sales.

We rely on third-party suppliers for certain of our raw materials, medical devices and components.

We rely on unaffiliated third-party suppliers for certain raw materials, medical devices and components necessary for the manufacturing of our commercial and clinical products. Certain of those raw materials, medical devices and components are proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug applications with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until the regulatory agency approved such supplier. For example, Insulet Corporation is our single source of the on-body injector for our Neulasta® Onpro® kit. Also, certain of the raw materials required in the commercial and clinical manufacturing of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues, bovine serum and human serum albumin.

Among the reasons we may be unable to obtain these raw materials, medical devices and components include:

- regulatory requirements or action by regulatory agencies or others;
- adverse financial or other strategic developments at or affecting the supplier, including bankruptcy;
- unexpected demand for or shortage of raw materials, medical devices or components;
- failure to comply with our quality standards which results in quality and product failures, product contamination and/or recall;
- a material shortage, contamination, recall and/or restrictions on the use of certain biologically derived substances or other raw materials;
- discovery of previously unknown or undetected imperfections in raw materials, medical devices or components; and
- labor disputes or shortages, including from the effects of health emergencies and natural disasters.

For example, in prior years we have experienced shortages in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility. Further quality issues that result in

unexpected additional demand for certain components may lead to shortages of required raw materials or components (such as we have experienced with EPOGEN® glass vials). We may experience similar or other shortages in the future resulting in delayed shipments, supply constraints, clinical trial delays, contract disputes and/or stock-outs of our products. These or other similar events could negatively impact our ability to satisfy demand for our products or conduct clinical trials, which could have a material adverse effect on our product use and sales and our business and results of operations.

Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. We currently are involved in the manufacture of many of our products and plan to manufacture many of our product candidates. In addition, we currently use third-party contract manufacturers to produce, or assist in the production of, a number of our products, and we currently use

contract manufacturers to produce, or assist in the production of, a number of our late-stage product candidates and drug delivery devices. See Item 1. Business—Manufacturing, Distribution and Raw Materials—Manufacturing. Our ability to adequately and timely manufacture and supply our products and product candidates is dependent on the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers, which may be impacted by:

- capacity of manufacturing facilities;
- contamination by microorganisms or viruses, or foreign particles from the manufacturing process;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of health emergencies or natural disasters;
- compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs and production success rates and yields;
- updates of manufacturing specifications;
- contractual disputes with our suppliers and contract manufacturers;
- timing and outcome of product quality testing;
- power failures and/or other utility failures; and/or
- breakdown, failure, substandard performance or improper installation or operation of equipment.

If the efficient manufacture and supply of our products or product candidates is interrupted, we may experience delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends, contract disputes and/or recalls of our products. From time to time we have initiated voluntary recalls of certain lots of our products. For example, in July 2014, we initiated a voluntary recall of an Aranesp® lot distributed in the EU after particles were detected in a quality control sample following distribution of that lot. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could have a material adverse effect on our product sales, business and results of operations.

Our manufacturing processes and those of our third-party contract manufacturers must undergo regulatory approval processes and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build, validate and license another manufacturing plant and it can take longer than three years to qualify and license a new contract manufacturer. We are in the process of commercially validating and licensing a second facility at our site in Singapore to enable the manufacture of the active pharmaceutical ingredient for KYPROLIS®. If we are unable to obtain needed licenses for this facility on a timely basis, it could adversely affect our ability to achieve our planned risk mitigation and cost reductions which, as a result, could have a material adverse effect on our product sales, business and results of operations.

If regulatory authorities determine that we or our third-party contract manufacturers or certain of our third-party service providers have violated regulations or if authorities restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. Such issues may also delay the approval of product candidates we have submitted for regulatory review, even if such product candidates are not directly related to the products, devices or processes at issue with regulators. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis or at all. If we or our third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers

fail to supply materials, products or services to us, we may experience delayed shipments, delays in our clinical trials, supply constraints, contract disputes, stock-outs and/or recalls of our products. Additionally, we distribute a substantial volume of our commercial products through our primary distribution centers in Louisville, Kentucky for the United States and in Breda, Netherlands for Europe and much of the rest of the world. We also conduct all the labeling and packaging of our products distributed in Europe and much of the rest of the world in Breda. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics centers, our third-party logistics providers and our labeling and packaging facility in Breda. Further, we rely on commercial transportation, including air freight, for the distribution of our products to our customers, which may be negatively impacted by natural disasters or security threats.

Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively impact our business.

Certain of our distributors, customers and payers have substantial purchasing leverage, due to the volume of our products they purchase or the number of patient lives for which they provide coverage. The substantial majority of our U.S. product sales is made to three pharmaceutical product wholesaler distributors: AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc. These distributors, in turn, sell our products to their customers, which include physicians or their clinics, dialysis centers, hospitals and pharmacies. One of our products, EPOGEN®, is sold primarily to free-standing dialysis clinics. DaVita owns or manages a large number of the outpatient dialysis facilities located in the United States and accounts for approximately 70% of all EPOGEN® sales. Similarly, as discussed above, there has been significant consolidation in the health insurance industry, including that a small number of PBMs now oversee a substantial percentage of total covered lives in the United States. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability*. The concentration of purchasing and negotiating power by these entities may put pressure on our pricing due to their ability to extract price discounts on our products, fees for other services or rebates, negatively impacting our bargaining position, sales and/or profit margins. In addition, decisions by these entities to purchase or cover less or none of our products in favor of competitive products could have a material adverse effect on our business and results of operations due to their purchasing volume. Further, if one of our significant wholesale distributors encounters financial or other difficulties and becomes unable or unwilling to pay us all amounts that such distributor owes us on a timely basis or at all, it could negatively impact our business and results of operations. In addition, if one of our significant wholesale distributors becomes insolvent or otherwise unable to continue its commercial relationship with us in its present form, it could significantly disrupt our business and adversely affect our product sales, our business and results of operations unless suitable alternatives are timely found or lost sales are absorbed by another distributor.

Our efforts to acquire other companies or products and to integrate their operations may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.

We seek innovation through significant investment in both internal R&D and external transactions including collaborations, partnering, alliances, licenses, joint ventures, mergers and acquisitions (acquisition activity). We have an ongoing process of evaluating such potential acquisition activity opportunities that we expect will contribute to our future growth and expand our geographic footprint, product offerings and/or our R&D pipeline. Acquisitions or similar arrangements may be complex, time consuming and expensive and may result in unanticipated costs, delays or other operational or financial problems related to integrating the acquired company and business with our company, which may result in the diversion of our management's attention from other business issues and opportunities. We may pay substantial amounts of cash, incur debt or issue equity securities to pay for acquisition activities, which could adversely affect our liquidity or result in dilution to our stockholders, respectively. Failures or difficulties in integrating or retaining new personnel or in integrating the operations of the businesses we acquire (including their technology, compliance programs, distribution and general business operations and procedures), while preserving important R&D, distribution, marketing, promotion and other relationships, may affect our ability to grow and may result in our incurring asset impairment or restructuring charges.

Our sales and operations are subject to the risks of doing business in emerging markets.

As we continue our expansion efforts in emerging markets around the world, through acquisitions and licensing transactions as well as through the development and introduction of our products in new markets, we face numerous risks to our business. There is no guarantee that our efforts and strategies to expand sales in emerging markets will succeed. Emerging market countries may be especially vulnerable to periods of global political, legal, regulatory and financial instability, including sovereign debt issues and/or the imposition of international sanctions in response to certain state actions. As we expand internationally, we are subject to fluctuations in foreign currency exchange rates relative to the U.S. dollar. While we have a program in place that is designed to reduce our exposure to foreign currency exchange rate fluctuations through foreign currency hedging arrangements, our hedging efforts do not completely offset the effect of these fluctuations on our revenues and earnings. We may also be required to increase our reliance on third-party agents and unfamiliar operations and arrangements previously utilized by companies we partner with or acquire in emerging markets. See *We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications*. Our international operations and business may also be subject to less protective intellectual property or other applicable laws, diverse data privacy and protection requirements, changing tax laws and tariffs, far-reaching anti-bribery and anti-corruption laws and regulations and/or evolving legal and regulatory environments. These legal and operational challenges along with government controls, the challenges of attracting and retaining qualified personnel and obtaining and/or maintaining

necessary regulatory or pricing approvals of our products may result in a material adverse impact on our international product sales, business and results of operations.

Our business may be affected by litigation and government investigations.

We and certain of our subsidiaries are involved in legal proceedings. See Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements. Civil and criminal litigation is inherently unpredictable, and the outcome can result in

costly verdicts, fines and penalties, exclusion from federal healthcare programs and/or injunctive relief that affect how we operate our business. Defense of litigation claims can be expensive, time-consuming and distracting, and it is possible that we could incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our business and results of operations. In addition, product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention and could adversely affect our reputation and the demand for our products. We and certain of our subsidiaries have previously been named as defendants in product liability actions for certain of our products.

We are also involved in government investigations that arise in the ordinary course of our business. In recent years, there has been a trend of increasing government investigations and litigations against companies operating in our industry, both in the United States and around the world. Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. As we announced on December 19, 2012, we finalized a settlement agreement with the U.S. government and various other parties to settle certain allegations regarding our sales and marketing practices. In connection with that settlement, we have been operating under a corporate integrity agreement with the OIG of the U.S. Department of Health and Human Services that requires us to maintain our corporate compliance program and to undertake a set of defined corporate integrity obligations until December 2017. The corporate integrity agreement also provides for an independent third-party review organization to assess and report on our compliance program. Certain of the corporate integrity agreement's reporting obligations to OIG continue into 2018. While we expect to fully comply with all of our obligations under the corporate integrity agreement, failure to do so could result in substantial penalties and our being excluded from government healthcare programs. We may see new government investigations of or actions against us citing novel theories of recovery. Any of these results could have a material adverse effect on our business and results of operations.

A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems and network-connected control systems and our data, interrupt the operation of our business and affect our reputation.

To achieve our business objectives, we rely to a large extent upon sophisticated information technology systems and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or affect our reputation.

Our information technology systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. The complexity and interconnected nature of our systems makes them potentially vulnerable to breakdown or other service interruptions. Our systems are also subject to frequent cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering and/or other means. Attacks such as those recently seen with other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access important data needed to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and distributing our products. For example, in 2017, Merck experienced a cyberattack involving virulent malware that significantly disrupted its operations, including the production of some of its medicines and vaccines. Our systems also contain and utilize a high volume of sensitive data, including intellectual property, trade secrets, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials or personal information belonging to us, our staff, our patients, customers and/or other business partners. In some cases, we utilize third-party service providers to manage or transmit such data, which may increase our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) by employees, service providers, nation states, organized crime organizations, "hacktivists" or others, pose risks that our sensitive data may be exposed to unauthorized persons, our competitors, or the public. Finally, domestic and global government regulators, our key business partners, suppliers with whom we do business, companies that provide us or our partners with important business services and companies we may acquire may face similar risks, and security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. For example, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers.

Although in the past we have experienced system breakdowns, attacks and information security breaches, we do not believe such breakdowns, attacks and breaches have had a material adverse effect on our operations. We continue to invest in the monitoring, protection, and resilience of our critical or sensitive data and systems. However, there can be no assurance that our efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks, or breaches of our systems that could adversely affect our business and operations and/ or result in the loss of critical or sensitive data, which could result in

financial, legal, business or reputational harm to us or impact our stock price. While we maintain cyber-liability insurance, our insurance is not sufficient to cover us against all losses that could potentially result from a service interruption, breach of our systems or loss of our critical or sensitive data.

Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Our operations and performance have been, and may continue to be, affected by global economic conditions. Financial pressures may cause government or other third-party payers to more aggressively seek cost containment measures. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability*. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships may also affect patients' ability to afford health care as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to reduced demand for our products, which could have a material adverse effect on our product sales, business and results of operations. Economic conditions may also adversely affect the ability of our distributors, customers and suppliers to obtain the liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Although we monitor our distributors', customers' and suppliers' financial condition and their liquidity to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could have a material adverse effect on our product sales, business and results of operations.

We maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our Consolidated Balance Sheets. The value of our investments may be adversely affected by interest rate fluctuations, downgrades in credit ratings, illiquidity in the capital markets and other factors that may result in other-than-temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on sales of investments.

Our stock price is volatile.

Our stock price, like that of our peers in the biotechnology and pharmaceutical industries, is volatile. Our revenues and operating results may fluctuate from period to period for a number of reasons. Events such as a delay in product development, changes to our expectations or strategy or even a relatively small revenue shortfall may cause financial results for a period to be below our expectations or projections. As a result, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Announcements or discussions of possible restrictive actions by government or private payers that would impact our business or industry if ultimately enacted or adopted may also cause our stock price to fluctuate, whether or not such restrictive actions ever actually occur. Similarly, actual or perceived safety issues with our products or similar products or unexpected clinical trial results can have an immediate and rapid impact on our stock price, whether or not our operating results are materially impacted.

We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The capital and credit markets may experience extreme volatility and disruption which may lead to uncertainty and liquidity issues for both borrowers and investors. We expect to access the capital markets to supplement our existing funds and cash generated from operations in satisfying our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. In the event of adverse capital and credit market conditions, we may be unable to obtain capital market financing on similar favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Changes in credit ratings issued by nationally recognized credit-rating agencies could adversely affect our ability to obtain capital market financing and the cost of such financing and have an adverse effect on the market price of our securities.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

As of December 31, 2017, we owned or leased approximately 180 properties. The locations and primary functions of significant properties are summarized in the following tables:

proptable.jpg

Excluded from the tables above are (i) undeveloped land and leased properties that have been abandoned and (ii) certain buildings that we still own but are no longer used in our business. There are no material encumbrances on our owned properties.

We believe that our facilities are suitable for their intended uses and, in conjunction with our third-party contracting manufacturing agreements, provide adequate capacity and are sufficient to meet our expected needs. See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

See Item 1. Business—Manufacturing, Distribution and Raw Materials.

Item 3. LEGAL PROCEEDINGS

Certain of the legal proceedings in which we are involved are discussed in Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements, and are hereby incorporated by reference.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Common stock

Our common stock trades on the NASDAQ Global Select Market under the symbol AMGN. As of February 9, 2018, there were approximately 6,070 holders of record of our common stock.

The following table sets forth, for the periods indicated, the range of high and low quarterly closing sales prices of the common stock as quoted on the NASDAQ Global Select Market:

Year ended December 31, 2017	High	Low
Fourth quarter	$ 188.59	$ 168.79
Third quarter	$ 191.00	$ 167.29
Second quarter	$ 174.07	$ 153.02
First quarter	$ 182.60	$ 150.73
Year ended December 31, 2016		
Fourth quarter	$ 168.31	$ 135.22
Third quarter	$ 175.62	$ 154.27
Second quarter	$ 164.35	$ 144.58
First quarter	$ 158.34	$ 140.90

Performance graph

The following graph shows the value of an investment of $100 on December 31, 2012, in each of Amgen common stock, the Amex Biotech Index, the Amex Pharmaceutical Index and Standard & Poor's 500 Index (S&P 500). All values assume reinvestment of the pretax value of dividends and are calculated as of December 31 of each year. The historical stock price performance of the Company's common stock shown in the performance graph is not necessarily indicative of future stock price performance.

Amgen vs. Amex Biotech, Amex Pharmaceutical and S&P 500 Indices

Comparison of Five-Year Cumulative Total Return

Value of Investment of $100 on December 31, 2012

a2017performancegraph.jpg

	12/31/2012	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017
Amgen (AMGN)	$100.00	$134.52	$191.45	$199.05	$184.03	$225.10
Amex Biotech (BTK)	$100.00	$150.77	$223.02	$248.42	$200.85	$276.79
Amex Pharmaceutical (DRG)	$100.00	$131.22	$152.97	$159.36	$146.07	$170.36
S&P 500 (SPX)	$100.00	$132.04	$150.11	$152.17	$170.36	$207.65

The material in this performance graph is not soliciting material, is not deemed filed with the SEC, and is not incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made on, before or after the date of this filing and irrespective of any general incorporation language in such filing.

Stock repurchase program

During the three months and year ended December 31, 2017, we had one outstanding stock repurchase program, under which the repurchasing activity was as follows:

	Total number of shares purchased	Average price paid per share[1]	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program[2]
October 1 - October 31	1,315,799	$ 181.90	1,315,799	$ 3,420,112,053
November 1 - November 30	1,851,275	$ 171.44	1,851,275	$ 4,609,000,103
December 1 - December 31	1,354,857	$ 176.55	1,354,857	$ 4,369,804,885
	4,521,931	$ 176.01	4,521,931	
January 1 - December 31	18,528,595	$ 168.71	18,528,595	

(1) Average price paid per share includes related expenses.

(2) In October 2017, our Board of Directors authorized an increase that resulted in a total of $5.0 billion available under our stock repurchase program. In January 2018, our Board of Directors authorized an additional $10.0 billion under our stock repurchase program.

Dividends

For the years ended December 31, 2017 and 2016, we paid quarterly dividends. We expect to continue to pay quarterly dividends, although the amount and timing of any future dividends are subject to approval by our Board of Directors. Additional information required by this item is incorporated herein by reference to Part IV—Note 15, Stockholders' equity, to the Consolidated Financial Statements.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

Information about securities authorized for issuance under existing equity compensation plans is incorporated by reference from Item 12—Securities Authorized for Issuance Under Existing Equity Compensation Plans.

Item 6. SELECTED FINANCIAL DATA

Consolidated Statements of Income Data:	Years ended December 31, 2017	2016	2015	2014	2013
	(In millions, except per share data)				
Revenues:					
Product sales	$ 21,795	$ 21,892	$ 20,944	$ 19,327	$ 18,192
Other revenues	1,054	1,099	718	736	484
Total revenues	$ 22,849	$ 22,991	$ 21,662	$ 20,063	$ 18,676
Operating expenses:					
Cost of sales	$ 4,069	$ 4,162	$ 4,227	$ 4,422	$ 3,346
Research and development	$ 3,562	$ 3,840	$ 4,070	$ 4,297	$ 4,083
Selling, general and administrative	$ 4,870	$ 5,062	$ 4,846	$ 4,699	$ 5,184
Net income[1]	$ 1,979	$ 7,722	$ 6,939	$ 5,158	$ 5,081
Diluted earnings per share[1]	$ 2.69	$ 10.24	$ 9.06	$ 6.70	$ 6.64
Dividends paid per share	$ 4.60	$ 4.00	$ 3.16	$ 2.44	$ 1.88

Consolidated Balance Sheets Data:	As of December 31, 2017	2016	2015	2014	2013
	(In millions)				
Total assets	$ 79,954	$ 77,626	$ 71,449	$ 68,882	$ 65,974
Total debt[2]	$ 35,342	$ 34,596	$ 31,429	$ 30,588	$ 31,977
Total stockholders' equity[3]	$ 25,241	$ 29,875	$ 28,083	$ 25,778	$ 22,096

In addition to the following notes, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and the Consolidated Financial Statements and accompanying notes and previously filed Annual Reports on Form 10-K for further information regarding our consolidated results of operations and financial position for periods reported therein and for known factors that will affect the comparability of future results. Also, see Part IV—Note 15, Stockholders' equity, to the Consolidated Financial Statements, for information regarding cash dividends declared per share of common stock for each of the four quarters of 2017, 2016, and 2015, respectively. In addition, our Board of Directors declared dividends per share of $0.61 and $0.47 that were paid in each of the four quarters of 2014 and 2013, respectively.

(1) In 2017, we recorded a net charge of $6.1 billion as a result of the 2017 Tax Act. See Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

(2) See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements, for discussion of our financing arrangements. In 2014, we issued $4.5 billion of debt and repaid $5.6 billion of debt. In 2013, we issued $8.1 billion of debt and repaid of $3.4 billion of debt.

(3) Throughout the five years ended December 31, 2017, we had a stock repurchase program authorized by the Board of Directors through which we repurchased $3.1 billion, $3.0 billion, $1.9 billion, $0.2 billion and $0.8 billion, respectively, of Amgen common stock.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis (MD&A) is intended to assist the reader in understanding Amgen's business. MD&A is provided as a supplement to, and should be read in conjunction with, our consolidated financial statements and accompanying notes. Our results of operations discussed in MD&A are presented in conformity with U.S. generally accepted accounting principles (GAAP). Amgen operates in one business segment: human therapeutics. Therefore, our results of operations are discussed on a consolidated basis.

Forward-looking statements

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. In addition, we, or others on our behalf, may make forward-looking statements in press releases or written statements, or in our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Such words as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume," and "continue," as well as variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and they involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in Item 1A. Risk Factors. We have based our forward-looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecast by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, earnings per share (EPS), liquidity and capital resources, trends, planned dividends, stock repurchases and restructuring plans. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

Amgen is a highly focused biotechnology company committed to unlocking the potential of biology for patients suffering from serious illnesses. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Our principal products (those products with the most significant annual commercial sales) include ENBREL, Neulasta®, Aranesp®, Prolia®, Sensipar®/Mimpara®, XGEVA® and EPOGEN®. We also market a number of other products, including KYPROLIS®, Vectibix®, Nplate®, NEUPOGEN®, Repatha®, BLINCYTO®, IMLYGIC®, Corlanor® and Parsabiv™. For additional information about our products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products.

Six therapeutic areas form the core of our business—oncology/hematology, cardiovascular disease, inflammation, bone health, nephrology and neuroscience. Our strategy to execute in these therapeutic areas is multifaceted as we engage in a series of integrated activities to strengthen our competitive position in the industry focused on seven strategic priorities:

strategicpriorities.jpg

In 2017, we made substantial progress on our strategic priorities.

- Our innovative pipeline continued to advance with the addition of cardiovascular outcomes data to the Repatha® label in the United States. The FDA also approved Parsabiv™ for secondary hyperparathyroidism in hemodialysis patients and Vectibix®, in combination with chemotherapy, for use in wild-type *RAS* metastatic colorectal cancer, and expanded the BLINCYTO® indication to include the treatment of relapsed or refractory B-cell precursor ALL in adults and children. We submitted the U.S. regulatory filing for Aimovig™ for the prevention of migraine in patients experiencing four or more migraines per month. We also made U.S. and EU regulatory filings to include overall survival data in the KYPROLIS® label for relapsed or refractory multiple myeloma patients and to expand the XGEVA® indication to include the prevention of SREs in patients with multiple myeloma. We announced positive phase 3 results for a weekly regimen of KYPROLIS® for the treatment of relapsed or refractory multiple myeloma and positive phase 2b results with tezepelumab, which has now advanced into Phase 3 for the treatment of severe, uncontrolled asthma. Throughout the course of the year, we invested in external early-stage innovation to augment our internal research efforts.

- Our biosimilars also continued to advance as the FDA approved MVASI™ for the treatment of five types of cancer, and the EC approved AMGEVITA™ for the treatment of certain inflammatory diseases. We also gained clarity on the launch timing of AMGEVITA™, which is now expected in Europe later this year and we submitted U.S. and EU regulatory filings for ABP 980.

- We continued to build the foundation for long-term growth through our product launches in new parts of the world, as seen by our ability to secure 80 country product launches, leveraging our global presence to deliver the potential of our products to patients.

- We continued to provide an uninterrupted supply of medicines for patients around the world while responding to natural disasters and investing for the future.

  - In September 2017, Hurricane Maria made landfall on the island of Puerto Rico. The hurricane caused widespread damage to the island, however, the critical manufacturing areas of our site in Juncos were not significantly impacted and we have resumed our full manufacturing operations.

  - We made investments in next-generation biomanufacturing that build on our expertise in human biology and protein manufacturing. This next-generation biomanufacturing dramatically reduces the scale and costs of making biologics while retaining a reliable, high-quality, compliant supply of medicines. In 2017, our new Singapore facility that uses our next-generation biomanufacturing technology was approved for certain commercial production by multiple regulatory agencies, including the FDA and the EMA.

- We continued to innovate with delivery systems to differentiate our products, as seen by our development of the AutoTouch™ reusable auto-injector to be used with Enbrel Mini™ single-dose prefilled cartridges (50 mg/mL), which was approved by the FDA in September 2017. This device was ergonomically designed to meet the needs of rheumatoid arthritis patients. We also launched our Repatha® automated mini-doser with pre-filled cartridge in Europe. This hands-free device provides Repatha® in a single injection for administration monthly. Further, the use of the Neulasta® Onpro® On-body Injector continues to increase, exiting 2017 with over 60% share of Neulasta® sales.

- Cash flows from operating activities grew 8% to $11.2 billion, enabling us to invest for the future and return capital to shareholders, consistent with our expectations for long-term growth. We increased our dividend 15% to $1.15 per share of common stock in each of the four quarters of 2017. In December 2017, the Board of Directors declared a cash dividend of $1.32 per share of common stock for the first quarter of 2018, an increase of 15% for this period, to be paid in March 2018. We also repurchased 18.5 million shares of our common stock throughout 2017 at an aggregate cost of $3.1 billion.

- We further optimized our business and operating model through significant transformation and process improvement efforts. Our transformation has established a foundation for growth and we are approaching the development of promising new medicines with greater understanding, speed and confidence.

Our 2017 financial results also reflect the impact of the 2017 Tax Act. We now have global access to our $41.7 billion balance of cash, cash equivalents and marketable securities, which unlocks additional financial flexibility.

While 2017 execution was strong, we expect 2018 will be another important year as we continue to invest in the pipeline, build our global business and support new product growth. In preparation for 2018, we expanded our transformation activities and savings initiatives to enable investment in new products and the defense of existing products to optimize long- and short-term growth. Our long-term success depends, to a great extent, on our ability to continue to discover, develop and commercialize innovative products and acquire or collaborate on therapies currently in development by other companies. We must develop new products over time in order to provide for revenue growth and to offset revenue losses when products lose their exclusivity or competing products are launched. Certain of our products will face increasing pressure from competition, including biosimilars and generics. For additional information, including information on the expiration of patents for various products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents and see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We devote considerable resources to R&D activities. However, successful product development in the biotechnology industry is highly uncertain. We are also confronted by increasing regulatory scrutiny of safety and efficacy both before and after products launch.

Rising healthcare costs and economic conditions also continue to pose challenges to our business, including continued pressure by third-party payers, such as governments and private payers, to reduce healthcare expenditures. As a result of public and private health care provider focus, the industry continues to experience significant pricing pressures and other cost containment measures.

Finally, wholesale and end-user buying patterns can affect our product sales. These effects can cause fluctuations in quarterly product sales and have generally not been significant when comparing full-year product performance to the prior year. See Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products

and Part I, Item 1A. Risk Factors for further discussion of certain of the factors that could impact our future product sales.

Selected Financial Information

The following is an overview of our results of operations (in millions, except percentages and per share data):

	Year ended December 31, 2017	Change	Year ended December 31, 2016
Product sales:			
U.S.	$ 17,131	(1%)	$ 17,325
Rest of world (ROW)	4,664	2 %	4,567
Total product sales	21,795	— %	21,892
Other revenues	1,054	(4%)	1,099
Total revenues	$ 22,849	(1%)	$ 22,991
Operating expenses	$ 12,876	(2%)	$ 13,197
Operating income	$ 9,973	2 %	$ 9,794
Net income	$ 1,979	(74%)	$ 7,722
Diluted EPS	$ 2.69	(74%)	$ 10.24
Diluted shares	735	(3%)	754

In the following discussion of changes in product sales, any reference to unit demand growth or decline refers to changes in the purchases of our products by healthcare providers, such as physicians or their clinics, dialysis centers, hospitals and pharmacies.

Total product sales for 2017 decreased slightly as a decline in U.S. product sales was offset partially by an increase in ROW product sales. The U.S. decrease was driven primarily by lower unit demand resulting from competition, offset partially by increases in net selling prices and favorable changes in inventory. The increase in ROW product sales for 2017 was driven primarily by higher unit demand, offset partially by unfavorable changes in foreign exchange rates and declines in net selling prices.

Operating expenses for 2017 decreased 2%. All expense categories benefited from savings resulting from our transformation and process improvement efforts.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is offset partially by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material in 2017, 2016 or 2015.

Results of Operations

Product sales

Worldwide product sales were as follows (dollar amounts in millions):

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
ENBREL	$ 5,433	(9 %)	$ 5,965	11 %	$ 5,364
Neulasta®	4,534	(2 %)	4,648	(1 %)	4,715
Aranesp®	2,053	(2 %)	2,093	7 %	1,951
Prolia®	1,968	20 %	1,635	25 %	1,312
Sensipar®/Mimpara®	1,718	9 %	1,582	12 %	1,415
XGEVA®	1,575	3 %	1,529	9 %	1,405
EPOGEN®	1,096	(15 %)	1,282	(31 %)	1,856
Other products	3,418	8 %	3,158	8 %	2,926
Total product sales	$ 21,795	— %	$ 21,892	5 %	$ 20,944
Total U.S.	$ 17,131	(1 %)	$ 17,325	5 %	$ 16,523
Total ROW	4,664	2 %	4,567	3 %	4,421
Total product sales	$ 21,795	— %	$ 21,892	5 %	$ 20,944

Future sales of our products will depend, in part, on the factors discussed in the Overview, Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition, in Part I, Item 1A. Risk Factors, and any additional factors discussed in the individual product sections below. In addition, for a list of our products' significant competitors, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition.

ENBREL

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
ENBREL — U.S.	$ 5,206	(9 %)	$ 5,719	12 %	$ 5,099
ENBREL — Canada	227	(8 %)	246	(7 %)	265
Total ENBREL	$ 5,433	(9 %)	$ 5,965	11 %	$ 5,364

The decrease in ENBREL sales for 2017 was driven primarily by lower unit demand and net selling price, offset partially by an increase in inventory. For 2018, we expect the trends of lower unit demand and net selling price to continue.

The increase in ENBREL sales for 2016 was driven primarily by an increase in net selling price, offset partially by the impact of competition.

Neulasta®

Total Neulasta® sales by geographic region were as follows (dollar amounts in millions):

	Change	Change

	Year ended December 31, 2017		Year ended December 31, 2016		Year ended December 31, 2015
Neulasta® — U.S.	$ 3,931	— %	$ 3,925	1 %	$ 3,891
Neulasta® — ROW	603	(17 %)	723	(12 %)	824
Total Neulasta®	$ 4,534	(2 %)	$ 4,648	(1 %)	$ 4,715

The decreases in global Neulasta® sales for 2017 and 2016 were driven primarily by lower unit demand, offset partially by an increase in net selling price in the United States. As of the end of December 2017, utilization of the Neulasta® Onpro® kit continues to grow in the United States.

Our final material U.S. patent for Neulasta® expired in October 2015. Therefore, we expect to face competition in the United States, which over time may have a material adverse impact on future sales of Neulasta®. Multiple companies have announced applications to the FDA for proposed biosimilar versions of Neulasta®. While a number of these companies have announced receipt of Complete Response Letters from the FDA regarding their applications, certain of these companies may receive approval in 2018. For discussion of ongoing patent litigations with these and other companies developing proposed biosimilar versions of Neulasta®, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

In addition, supplementary protection certificates issued by certain countries, including France, Germany, Italy, Spain and the United Kingdom, relating to our European patent for Neulasta® expired in August 2017. For further information regarding our patents, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents.

Neulasta® sales have been and will continue to be impacted by the development of new protocols, tests and/or treatments for cancer and/or new treatment alternatives that have reduced and may continue to reduce the use of myelosuppressive regimens in some patients.

Aranesp®

Total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
Aranesp® — U.S.	$ 1,114	3 %	$ 1,082	20 %	$ 900
Aranesp® — ROW	939	(7 %)	1,011	(4 %)	1,051
Total Aranesp®	$ 2,053	(2 %)	$ 2,093	7 %	$ 1,951

The decrease in global Aranesp® sales for 2017 was driven primarily by unfavorable changes in foreign currency exchange rates, offset partially by higher unit demand, including a shift of some U.S. dialysis centers from EPOGEN®.

The increase in global Aranesp® sales for 2016 was driven primarily by higher unit demand, including a shift of some U.S. dialysis centers from EPOGEN®, offset partially by a decrease in net selling price in ROW.

For 2018, we expect Aranesp® to face increasing competition from branded products. We could also face competition from biosimilar versions of EPOGEN® in 2018 if they launch in the United States.

Prolia®

Total Prolia® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
Prolia® — U.S.	$ 1,272	21 %	$ 1,049	25 %	$ 837
Prolia® — ROW	696	19 %	586	23 %	475
Total Prolia®	$ 1,968	20 %	$ 1,635	25 %	$ 1,312

The increases in global Prolia® sales for 2017 and 2016 were driven primarily by higher unit demand.

Sensipar®/Mimpara®

Total Sensipar®/Mimpara® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
Sensipar® — U.S.	$ 1,374	11 %	$ 1,240	16 %	$ 1,069

Sensipar®/Mimpara® — ROW	344	1 %	342	(1 %)	346
Total Sensipar®/Mimpara®	$ 1,718	9 %	$ 1,582	12 %	$ 1,415

The increases in global Sensipar®/Mimpara® sales for 2017 and 2016 were driven primarily by an increase in net selling price in the United States and, to a lesser extent, higher unit demand.

Our U.S. composition of matter patent relating to Sensipar®, a small molecule, expires in March 2018. We are also involved in a number of litigation matters relating to Sensipar®, including patent litigations with a number of companies seeking to market generic versions of Sensipar® and litigation regarding our request for pediatric exclusivity for Sensipar®. See Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

XGEVA®

Total XGEVA® sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
XGEVA® — U.S.	$ 1,157	4%	$ 1,115	11%	$ 1,006
XGEVA® — ROW	418	1%	414	4%	399
Total XGEVA®	$ 1,575	3%	$ 1,529	9%	$ 1,405

The increases in global XGEVA® sales for 2017 and 2016 were driven primarily by higher unit demand.

EPOGEN®

Total EPOGEN® sales were as follows (dollar amounts in millions):

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
EPOGEN® — U.S.	$ 1,096	(15%)	$ 1,282	(31%)	$ 1,856

The decrease in EPOGEN® sales for 2017 was driven primarily by a decline in net selling price due to contractual terms negotiated with DaVita (see Part I, Item 1. Business—Business Relationships) and, to a lesser extent, a shift in some U.S. dialysis centers to Aranesp®.

The decrease in EPOGEN® sales for 2016 was driven by a decline in unit demand resulting from competition and a shift in some U.S. dialysis centers to Aranesp®.

Our final material U.S. patent for EPOGEN® expired in May 2015. We face competition in the United States, which has had, and will continue to have, a material adverse impact on sales of EPOGEN®. Multiple companies are developing proposed biosimilar versions of EPOGEN® and certain of these companies may receive approval in 2018. For discussion of ongoing patent litigation with this company, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

Other products

Other product sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
KYPROLIS® — U.S.	$ 562	1 %	$ 554	19 %	$ 467
KYPROLIS® — ROW	273	98 %	138	*	45
Vectibix® — U.S.	251	10 %	229	12 %	204
Vectibix® — ROW	391	2 %	382	11 %	345
Nplate® — U.S.	392	12 %	350	10 %	317
Nplate® — ROW	250	7 %	234	13 %	208
NEUPOGEN® — U.S.	369	(31 %)	534	(33 %)	793
NEUPOGEN® — ROW	180	(22 %)	231	(10 %)	256
Repatha® — U.S.	225	*	101	*	7
Repatha® — ROW	94	*	40	*	3
BLINCYTO® — U.S.	114	34 %	85	27 %	67
BLINCYTO® — ROW	61	*	30	*	10
Other — U.S.	68	13 %	60	*	10
Other — ROW	188	(1 %)	190	(2 %)	194
Total other product sales	$ 3,418	8 %	$ 3,158	8 %	$ 2,926
Total U.S. — other products	$ 1,981		$ 1,913		$ 1,865
Total ROW — other products	1,437		1,245		1,061
Total other product sales	$ 3,418		$ 3,158		$ 2,926

* Change in excess of 100%

Operating expenses

Operating expenses were as follows (dollar amounts in millions):

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
Operating expenses:					
Cost of sales	$ 4,069	(2 %)	$ 4,162	(2 %)	$ 4,227
% of product sales	18.7 %		19.0 %		20.2 %
% of total revenues	17.8 %		18.1 %		19.5 %
Research and development	$ 3,562	(7 %)	$ 3,840	(6 %)	$ 4,070
% of product sales	16.3 %		17.5 %		19.4 %
% of total revenues	15.6 %		16.7 %		18.8 %
Selling, general and administrative	$ 4,870	(4 %)	$ 5,062	4 %	$ 4,846
% of product sales	22.3 %		23.1 %		23.1 %
% of total revenues	21.3 %		22.0 %		22.4 %
Other	$ 375	*	$ 133	*	$ 49

* Change in excess of 100%

Transformation and process improvement

During 2014, we announced transformation and process improvement efforts that we continue to execute. As part of these efforts, we committed to a more agile and efficient operating model. Our transformation and process improvement efforts across the Company are enabling us to reallocate resources to fund many of our innovative pipeline and growth opportunities that deliver value to patients and stockholders.

The transformation includes a restructuring plan that we continue to estimate will result in pre-tax accounting charges in the range of $825 million to $900 million. As of December 31, 2017, restructuring costs incurred to date were $797 million. During 2017, 2016 and 2015, we incurred restructuring costs of $88 million, $37 million and $114 million, respectively. We expect that we will incur most of the remaining estimated costs in 2018 in order to support our ongoing transformation and process improvement efforts. Since 2014, we have realized approximately $1.5 billion of transformation and process improvement savings. Net savings have not been significant as savings were reinvested in product launches, clinical programs and external business development. Additional information required for our restructuring plan is incorporated herein by reference to Part IV—Note 2, Restructuring, to the Consolidated Financial Statements.

Puerto Rico operations

In September 2017, Hurricane Maria made landfall on the island of Puerto Rico. The hurricane caused widespread damage to the island and some damage to our facility in Juncos. Critical manufacturing areas of our facility were not significantly affected, and we have resumed our full manufacturing operations. Further recovery efforts on the island are ongoing. We have continued to provide an uninterrupted supply of medicines for patients around the world. See Part I, Item 1A. Risk Factors—*We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and substantially all of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.*

We incurred $146 million of pre-tax expenses in 2017 related to Hurricane Maria. At this time, we do not expect significant pre-tax expenses in 2018.

Cost of sales

Cost of sales decreased to 17.8% of total revenues for 2017, driven primarily by lower amortization of intangible assets, lower royalties and favorable manufacturing costs, offset partially by expenses related to Hurricane Maria, unfavorable product mix and other inventory costs.

Cost of sales decreased to 18.1% of total revenues for 2016, driven primarily by certain manufacturing efficiencies.

Research and development

The Company groups all of its R&D activities and related expenditures into three categories: (1) Discovery Research and Translational Sciences (DRTS), (2) later-stage clinical programs and (3) marketed products. These categories include the Company's R&D activities as set forth in the following table:

Category	Description
DRTS	R&D expenses incurred in activities substantially in support of early research through the completion of phase 1 clinical trials. These activities encompass our DRTS functions, including drug discovery, toxicology, pharmacokinetics and drug metabolism, and process development.
Later-stage clinical programs	R&D expenses incurred in or related to phase 2 and phase 3 clinical programs intended to result in registration of a new product or a new indication for an existing product in the United States or the EU.
Marketed products	R&D expenses incurred in support of the Company's marketed products that are authorized to be sold in the United States or the EU. Includes clinical trials designed to gather information on product safety (certain of which may be required by regulatory authorities) and their product characteristics after regulatory approval has been obtained, as well as the costs of obtaining regulatory approval of a product in a new market after approval in either the United States or the EU has been obtained.

R&D expense by category was as follows (in millions):

	Years ended December 31,		
	2017	2016	2015
DRTS	$ 972	$ 1,039	$ 997
Later-stage clinical programs	879	1,054	1,876
Marketed products	1,711	1,747	1,197
Total R&D expense	$ 3,562	$ 3,840	$ 4,070

The decrease in R&D expenses for 2017 was driven by decreased costs associated with later-stage clinical program support, lower external business development expense in DRTS and lower marketed-product support. All categories of R&D spend benefited from savings from transformation and process improvement efforts and we continue to advance our pipeline.

The decrease in R&D expenses for 2016 was driven primarily by decreased costs associated with later-stage clinical programs support of $822 million, offset partially by increased costs associated with marketed-products support of $550 million. All categories of R&D spend benefited from savings from transformation and process improvement efforts. The decrease was offset partially by reinvestment for the long-term benefit of the company, including an increase in DRTS for up-front milestone payments related to several collaboration transactions. Prior to approval, costs related to our launch products were categorized largely as later-stage clinical programs.

Selling, general and administrative

The decrease in Selling, general and administrative (SG&A) expense for 2017 was driven primarily by the expiration of the ENBREL residual royalty payments on October 31, 2016, offset partially by investments in product launch and marketed product support.

The increase in SG&A expense for 2016 was driven primarily by further investments in product launches, offset partially by the expiration of the ENBREL residual royalty payments on October 31, 2016.

The ENBREL co-promotion term expired in October 2013, and we were required to pay Pfizer residual royalties on a declining percentage of net ENBREL sales in the United States and Canada. Effective November 2016, there were no further residual royalty payments. The residual royalty percentage ranged from 10% to 11% in 2016 and 2015.

Other

Other operating expenses for 2017 included $284 million of net charges associated with the discontinuance of the internal development of AMG 899 and $83 million of certain net charges related to our restructuring plan. See Part IV—Note 3, Business combinations, to the Consolidated Financial Statements.

Other operating expenses for 2016 included $105 million of charges related to legal proceedings.

Other operating expenses for 2015 included $91 million of charges related to legal proceedings; certain charges related to our restructuring initiatives, including separation costs of $49 million; $31 million of write-offs of non-key assets acquired in a prior-year business combination; and $111 million of gains from the sale of assets related to our site closures.

Non-operating expenses, income and provision for income taxes

Non-operating expenses, income and provision for income taxes were as follows (dollar amounts in millions):

	Years ended December 31,		
	2017	2016	2015
Interest expense, net	$ 1,304	$ 1,260	$ 1,095
Interest and other income, net	$ 928	$ 629	$ 603
Provision for income taxes	$ 7,618	$ 1,441	$ 1,039
Effective tax rate	79.4 %	15.7 %	13.0 %

Interest expense, net

The increases in interest expense, net in 2017 and 2016 were due primarily to a higher average amount of debt outstanding compared with the respective prior year.

Interest and other income, net

The increase in interest and other income, net for 2017 compared with 2016 was due primarily to higher interest income that resulted from higher average investment balances and higher gains on strategic investments.

The increase in interest and other income, net for 2016 compared with 2015 was due primarily to higher interest income as a result of higher average investment balances in 2016, offset partially by higher gains on strategic equity investments in 2015.

Income taxes

The increase in our effective tax rate for 2017 compared with 2016 was due primarily to impacts of the 2017 Tax Act, including the repatriation tax on accumulated foreign earnings, offset partially by the remeasurement of certain net deferred and other tax liabilities.

The increase in our effective tax rate for 2016 compared with 2015 was due primarily to the unfavorable tax impact of changes in jurisdictional mix of income and expenses, offset partially by the adoption of a new accounting standard that amends certain aspects of the accounting for employee share-based compensation payments. One aspect of the standard requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized as an income tax benefit and expense in the income statement.

On December 22, 2017, the United States enacted the 2017 Tax Act that imposes a repatriation tax on accumulated earnings of foreign subsidiaries, implements a territorial tax system together with a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (SAB 118) that allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We currently are analyzing the 2017 Tax Act, and in certain areas, have made reasonable estimates of the effects on our consolidated financial statements and tax disclosures, including the amount of the repatriation tax and changes to our existing deferred tax balances.

The repatriation tax is based primarily on our accumulated foreign earnings and profits that we previously deferred from U.S. income taxes. We recorded an estimated amount for our repatriation tax liability of $7.3 billion as of December 31, 2017. We no longer reinvest our undistributed earnings of our foreign operations indefinitely outside the United States. In addition, we remeasured certain net deferred and other tax liabilities based on the tax rates at which they are expected to reverse in the future. The estimated amount recorded related to the remeasurement of these balances was a net benefit of $1.2 billion. The net estimated impact of the 2017 Tax Act is $6.1 billion.

We consider the key estimates on the repatriation tax, net deferred tax remeasurement and the impact on our unrealized tax benefits to be incomplete due to our continuing analysis of final year-end data and tax positions. Our analysis could affect the measurement of these balances and give rise to new deferred tax assets and liabilities. Since the 2017 Tax Act was passed late in the fourth quarter of 2017, and further guidance and accounting interpretation is expected over the next 12 months, our review is still pending. We expect to complete our analysis within the measurement period.

As previously disclosed, we received a RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. On November 29, 2017, we received a modified RAR that revised their calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution through the IRS administrative appeals process, which we believe will likely not be concluded within the next 12 months. Final resolution of the IRS audit could have a material impact on our results of consolidated operations and cash flows if not resolved favorably, however, we believe our income tax reserves are appropriately provided for all open tax years.

See Summary of Critical Accounting Policies—Income taxes, and Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

Financial Condition, Liquidity and Capital Resources

Selected financial data was as follows (in millions):

	December 31,	
	2017	2016
Cash, cash equivalents and marketable securities	$ 41,678	$ 38,085
Total assets	$ 79,954	$ 77,626
Short-term borrowings and current portion of long-term debt	$ 1,152	$ 4,403
Long-term debt	$ 34,190	$ 30,193
Stockholders' equity	$ 25,241	$ 29,875

Cash, cash equivalents and marketable securities

We now have global access to our $41.7 billion balance of cash, cash equivalents and marketable securities, as we no longer reinvest our undistributed foreign earnings indefinitely outside the United States. Under the 2017 Tax Act, we owe a repatriation tax on undistributed earnings generated from operations in foreign tax jurisdictions estimated at $7.3 billion that will be paid over eight years. See Contractual Obligations below. We will also have access to global cash generated from operations in the future.

The primary objective of our investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings and places restrictions on maturities and concentration by asset class and issuer.

Capital allocation

Consistent with the objective to optimize our capital structure, we will seek to deploy our accumulated cash balances in an efficient manner and will consider several alternatives such as share repurchases, payment of cash dividends, repayment of debt, and strategic transactions that expand our portfolio of products in areas of therapeutic interest.

In addition to deploying our cash balances, we intend to continue to invest in our business and return capital to stockholders through the payment of cash dividends and stock repurchases reflecting our confidence in the future cash flows of our business. The timing and amount of future dividends and stock repurchases will vary based on a number of factors, including future capital requirements for strategic transactions, the availability of financing on acceptable terms, debt service requirements, our credit rating, changes to applicable tax laws or corporate laws, changes to our business model and periodic determination by our Board of Directors that cash dividends and/or stock repurchases are in the best interests of stockholders and are in compliance with applicable laws and agreements of the Company. In addition, the timing and amount of stock repurchases may also be affected by the stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include private block purchases, tender offers and market transactions.

The Board of Directors declared quarterly cash dividends of $0.79 per share of common stock in 2015, increased our quarterly cash dividend by 27% to $1.00 per share of common stock in 2016, and increased our quarterly cash dividend by 15% to $1.15 per share of common stock in 2017. In December 2017, the Board of Directors declared a cash dividend of $1.32 per share of common stock for the first quarter of 2018, an increase of 15% for this period, to be paid in March 2018.

We have also returned capital to stockholders through our stock repurchase program. During 2017, we repurchased $3.1 billion of common stock and had cash settlements of $3.2 billion. In 2016 and 2015, we repurchased $3.0 billion and $1.9 billion of our common stock, respectively. As of December 31, 2017, $4.4 billion remained available under the stock repurchase program.

In January 2018, our Board of Directors authorized an additional $10.0 billion under our stock repurchase program. Based on our confidence in the long-term outlook for our business, enhanced by the 2017 Tax Act, and consistent with our ongoing objective to return capital to our stockholders, on February 5, 2018, we announced a tender offer to purchase up to $10.0 billion of our common stock at a price not greater than $200 per share nor less

than $175 per share. The tender offer expires at 12:00 Midnight, New York City time, at the end of Monday, March 5, 2018, unless the offer is extended.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt

markets and equity markets. See Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business*.

Financing arrangements

The current and noncurrent portions of our long-term borrowings as of December 31, 2017, were $1.2 billion and $34.2 billion, respectively. The current and noncurrent portions of our long-term borrowings as of December 31, 2016, were $4.4 billion and $30.2 billion, respectively. As of December 31, 2017, Standard & Poor's Financial Services LLC (S&P), Moody's Investors Service, Inc. (Moody's) and Fitch Ratings Inc. (Fitch) assigned credit ratings to our outstanding senior notes of A with a stable outlook, Baa1 with a stable outlook and BBB with a stable outlook, respectively, which are considered investment grade. Unfavorable changes to these ratings may have an adverse impact on future financings.

During 2017, 2016 and 2015, we issued debt with aggregate principal amounts of $4.5 billion, $7.3 billion and $3.5 billion, respectively. During 2017, 2016 and 2015, we repaid debt of $4.4 billion, $3.7 billion and $2.4 billion, respectively.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating London Interbank Offered Rates (LIBOR)-based coupon over the life of the respective note. These interest rate swap contracts qualified and are designated as fair value hedges. As of December 31, 2017 and 2016, we had interest rate swap contracts with aggregate notional amounts of $9.45 billion and $6.65 billion, respectively.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts, which effectively convert the interest payments and principal repayment of the respective notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts qualified and are designated as cash flow hedges. As of December 31, 2017 and 2016, we had cross-currency swap contracts with aggregate notional amounts of $5.6 billion.

As of December 31, 2017, we had a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. During 2017, we issued and repaid an aggregate of $12.3 billion commercial paper and had a maximum outstanding balance of $1.5 billion under our commercial paper program. During 2016 and 2015, we did not issue any commercial paper. No commercial paper was outstanding as of December 31, 2017 or 2016.

In 2014, we entered into a $2.5 billion syndicated, unsecured, revolving credit agreement which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $500 million with the agreement of the banks. Each bank which is a party to the agreement has an initial commitment term of five years. We extended this term by one year during 2016 and may extend the term for an additional year with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest at LIBOR plus 1% for any amounts borrowed under this facility. As of December 31, 2017 and 2016, no amounts were outstanding under this facility.

In 2017, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2020.

Certain of our financing arrangements contain non-financial covenants. In addition, our revolving credit agreement includes a financial covenant with respect to the level of our borrowings in relation to our equity, as defined. We were in compliance with all applicable covenants under this arrangement as of December 31, 2017.

See Part IV—Note 14, Financing arrangements, and Note 17, Derivative instruments, to the Consolidated Financial Statements.

Cash flows

A summary of our cash flow activity was as follows (in millions):

	Years ended December 31,		
	2017	2016	2015
Net cash provided by operating activities	$ 11,177	$ 10,354	$ 9,731
Net cash used in investing activities	$ (4,024)	$ (8,658)	$ (5,547)
Net cash used in financing activities	$ (6,594)	$ (2,599)	$ (3,771)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities increased during 2017 due primarily to a higher operating margin and the timing of payments to vendors and receipts from customers, offset partially by higher payments to taxing authorities. Cash provided by operating activities increased during 2016 due primarily to an improved operating margin and the timing of customer payments, offset partially by inventory build, the monetization of foreign currency forward contracts in 2015 and the timing of tax payments.

Investing

Cash used in investing activities during 2017, 2016 and 2015 was due primarily to net cash outflows related to marketable securities of $3.2 billion, $7.7 billion and $4.4 billion, respectively. Capital expenditures, which were associated primarily with site development costs, including our Thousand Oaks campus, as well as manufacturing capacity expansions in Puerto Rico, Singapore and Ireland, were $664 million, $738 million and $594 million in 2017, 2016 and 2015, respectively. We currently estimate 2018 spending on capital projects to be approximately $750 million.

Financing

Cash used in financing activities during 2017 was due primarily to the repayment of debt of $4.4 billion, the payment of dividends of $3.4 billion, repurchases of our common stock of $3.2 billion and withholding taxes arising from shares withheld for share-based payments of $191 million, offset partially by net proceeds from the issuance of debt of $4.5 billion. Cash used in financing activities during 2016 was due primarily to the repayment of debt of $3.7 billion, the payment of dividends of $3.0 billion, repurchases of our common stock of $3.0 billion and withholding taxes arising from shares withheld for share-based payments of $260 million, offset partially by net proceeds from the issuance of debt of $7.3 billion. Cash used in financing activities during 2015 was due primarily to the repayment of debt of $2.4 billion, the payment of dividends of $2.4 billion, repurchases of our common stock of $1.9 billion, withholding taxes arising from shares withheld for share-based payments of $401 million and the settlement of contingent consideration obligations incurred in connection with the acquisition of a business of $253 million, offset partially by net proceeds from the issuance of debt of $3.5 billion.

See Part IV—Note 14, Financing arrangements, and Note 15, Stockholders' equity, to the Consolidated Financial Statements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are material or reasonably likely to become material to our consolidated financial position or consolidated results of operations.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payment. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information. Timing of payments and actual amounts paid may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations.

The following table represents our contractual obligations aggregated by type (in millions):

	Payments due by period as of December 31, 2017				
Contractual obligations	**Total**	**Year 1**	**Years 2 and 3**	**Years 4 and 5**	**Years 6 and beyond**
Long-term debt obligations (1) (2) (3) (4)	$ 56,763	$ 2,530	$ 9,964	$ 9,705	$ 34,564
Operating lease obligations (5)	650	158	242	159	91
Purchase obligations (6)	1,343	605	346	150	242
U.S. repatriation tax (7)	7,316	585	1,170	1,170	4,391
Unrecognized tax benefits (UTBs) (8)	—	—	—	—	—
Total contractual obligations	$ 66,072	$ 3,878	$ 11,722	$ 11,184	$ 39,288

(1) Long-term debt obligations include future interest payments on our fixed-rate obligations at the contractual coupon rates. To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the life of the respective note. We used an interest rate forward curve as of December 31, 2017, in computing net amounts to be paid or received under our interest rate swap contracts which resulted in an aggregate net increase in future interest payments of $22 million. See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements.

(2) Long-term debt obligations include future interest payments on our LIBOR-based variable-rate obligations. We used an interest rate forward curve as of December 31, 2017, in computing the LIBOR-based portion of interest payments on these debt obligations. See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements.

(3) Long-term debt obligations include contractual interest payments and principal repayment of our foreign-denominated debt obligations. In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our euro, pound sterling and Swiss franc denominated long-term debt, we entered into cross-currency swap contracts that effectively convert interest payments and principal repayment on this debt from euros, pounds sterling and Swiss francs to U.S. dollars. For purposes of this table, we used the contracted exchange rates in the cross-currency swap contracts to compute the net amounts of future interest payments and principal repayments on this debt. See Part IV—Note 17, Derivative instruments, to the Consolidated Financial Statements.

(4) Interest payments and the repayment of principal on our 4.375% 2018 euro Notes were translated into U.S. dollars at the foreign currency exchange rate in effect as of December 31, 2017. See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements.

(5) Operating lease obligations exclude $205 million of future receipts under noncancelable subleases of abandoned facilities.

(6) Purchase obligations relate primarily to: (i) R&D commitments (including those related to clinical trials) for new and existing products; (ii) capital expenditures; and (iii) open purchase orders for the acquisition of goods and services in the ordinary course of business. Our obligation to pay certain of these amounts may be reduced based on certain future events.

(7) Under the 2017 Tax Act, we will elect to pay the repatriation tax primarily related to our prior indefinitely invested earnings of our foreign operations in eight annual installments beginning April 2018. See Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

(8) Liabilities for UTBs (net of foreign tax credits and federal tax benefit of state taxes) and related accrued interest and penalties of $2.4 billion as of December 31, 2017, are not included in the table above because, due to their nature, there is a high degree of uncertainty regarding the timing of future cash outflows and other events that extinguish these liabilities.

In addition to amounts in the table above, we are contractually obligated to pay additional amounts, which in the aggregate are significant, upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties, including contingent consideration incurred in the acquisition of BioVex Group Inc. (BioVex). These payments are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring. These contingent payments have not been included in the table above, and, except with respect to the fair value of the contingent consideration obligations, are not recorded on our Consolidated Balance Sheets. As of December 31, 2017, the maximum amount that may be payable in the future for agreements we have entered into with third parties is $7.0 billion, including $325 million of contingent consideration payments in connection with the acquisition of BioVex. Contingent consideration with respect to the acquisition of Dezima Pharma B.V. was excluded due to the discontinuation of the development of AMG 899, upon which payments are based. See Part IV—Note 16, Fair value measurement, to the Consolidated Financial Statements.

Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

Product sales and sales deductions

Revenues from sales of our products are recognized when the products are shipped and title and risk of loss have passed. Product sales are recorded net of accruals for estimated rebates, wholesaler chargebacks, cash discounts and other deductions (collectively, sales deductions) and returns, which are established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate. Accruals are also adjusted to reflect actual results. Amounts recorded in Accrued liabilities in the Consolidated Balance Sheets for sales deductions were as follows (in millions):

	Rebates	Chargebacks	Other deductions	Total
Balance as of December 31, 2014	$ 1,120	$ 196	$ 63	$ 1,379
Amounts charged against product sales	2,734	4,275	732	7,741
Payments	(2,735)	(4,198)	(701)	(7,634)
Balance as of December 31, 2015	1,119	273	94	1,486
Amounts charged against product sales	3,479	5,270	905	9,654
Payments	(3,181)	(5,201)	(884)	(9,266)
Balance as of December 31, 2016	1,417	342	115	1,874
Amounts charged against product sales	4,909	6,098	992	11,999
Payments	(4,459)	(6,168)	(999)	(11,626)
Balance as of December 31, 2017	$ 1,867	$ 272	$ 108	$ 2,247

For the years ended December 31, 2017, 2016 and 2015, total sales deductions were 35%, 31% and 27% of gross product sales, respectively. Included in the amounts are immaterial net adjustments related to prior-year sales due to changes in estimates. Such amounts represent less than 1% of the aggregate sales deductions charged against product sales in each of the three years ended December 31, 2017.

In the United States, we utilize wholesalers as the principal means of distributing our products to healthcare providers, such as physicians or their clinics, dialysis centers, hospitals and pharmacies. Products we sell in Europe are distributed principally to hospitals and/or wholesalers depending on the distribution practice in each country where the product is sold. We monitor the inventory levels of our products at our wholesalers by using data from our wholesalers and other third parties, and we believe wholesaler inventories have been maintained at appropriate levels (generally two to three weeks) given end-user demand. Accordingly, historical fluctuations in wholesaler inventory levels have not significantly impacted our method of estimating sales deductions and returns.

Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and, therefore, for any given year, can be impacted by the mix of products sold.

Rebates include primarily amounts paid to payers and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements which vary by product, by payer and by individual payer plans. As we sell product, we estimate the amount of rebate we will pay based on the product sold, contractual terms, estimated patient population, historical experience and wholesaler inventory levels and accrue these rebates in the period the related sale is recorded. We then adjust the rebate accruals as more information becomes available and to reflect actual claims experience. Estimating such rebates is complicated, in part because of the time delay between the date of sale and the actual settlement of the liability. We believe the methodology we use to accrue for rebates is reasonable and appropriate given current facts and circumstances, but actual results may differ.

Wholesaler chargebacks relate to our contractual agreements to sell products to healthcare providers in the United States at fixed prices that are lower than the prices we charge wholesalers. When healthcare providers purchase our products through wholesalers at these reduced prices, wholesalers charge us for the difference between their purchase price and the contractual price

between Amgen and the healthcare providers. The provision for chargebacks is based on the expected sales by our wholesaler customers to healthcare providers. Accruals for wholesaler chargebacks are less difficult to estimate than rebates and closely approximate actual results since chargeback amounts are fixed at the date of purchase by the healthcare providers, and we generally settle the liability for these deductions within a few weeks.

Product returns

Returns are estimated through comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. In each of the past three years, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-year sales return provisions have historically been insignificant.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates available in the various jurisdictions in which we operate.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements on a particular tax position is measured based on the largest benefit that is more likely than not to be realized. The amount of UTBs is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We believe our estimates for uncertain tax positions are appropriate and sufficient for any assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense.

Certain items are included in our tax return at different times than they are reflected in the financial statements and cause temporary differences between the tax bases of assets and liabilities and their reported amounts. Such temporary differences create deferred tax assets and liabilities. Deferred tax assets are generally items that can be used as a tax deduction or credit in the tax return in future years but for which we have already recorded the tax benefit in the consolidated financial statements. We establish valuation allowances against our deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities are either: (i) tax expenses recognized in the consolidated financial statements for which payment has been deferred; (ii) expenses for which we have already taken a deduction on the tax return, but have not yet recognized the expense in the consolidated financial statements; or (iii) liabilities for the difference between the book basis and tax basis of the intangible assets acquired in many business combinations, as future expenses associated with these assets most often will not be tax deductible.

We are a vertically integrated enterprise with operations in the United States and various foreign jurisdictions. We are subject to income tax in the foreign jurisdictions where we conduct activities based on the tax laws and principles of such jurisdictions and the functions, risks and activities performed therein. Our pretax income is therefore attributed to domestic or foreign sources based on the operations performed and risks assumed in each location and the tax laws and principles of the respective taxing jurisdictions. For example, we conduct significant operations in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes, pertaining to manufacturing, distribution and other related functions to meet our worldwide product demand. Income from our operations in Puerto Rico is subject to tax incentive grants through 2035.

On December 22, 2017, the SEC staff issued SAB 118 to address the accounting implications of the 2017 Tax Act. The effects of the 2017 Tax Act are recognized upon enactment, however, SAB 118 permits a company to recognize provisional amounts when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law. The measurement period to finalize our calculations cannot extend beyond one year of the enactment date. Key provisions that have a significant impact on our consolidated financial statements and where we have recognized estimated amounts include the recognition of liabilities for taxes on repatriation of accumulated foreign earnings and the remeasurement of certain net deferred and other tax liabilities.

Furthermore, the 2017 Tax Act permits a company, upon election, to pay the repatriation tax over eight years on an interest-free basis, which we expect to do. In January 2018, the Financial Accounting Standards Board staff issued Staff Q&A, Topic 740, No. 2, Whether to Discount the Tax Liability on Deemed Repatriation, which notes that the

repatriation tax liability should not be discounted. See Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

Our operations are subject to the tax laws, regulations and administrative practices of the United States, U.S. state jurisdictions and other countries, including the U.S. territory of Puerto Rico, in which we do business. Significant changes in these rules could have a material adverse effect on our results of operations. See Part I, Item 1A. Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability*.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings and other matters such as intellectual property disputes, contractual disputes, governmental investigations and class action suits which are complex in nature and have outcomes that are difficult to predict. Certain of these proceedings are discussed in Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We consider all relevant factors when making assessments regarding these contingencies.

While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Valuation of assets and liabilities in connection with business combinations

We have acquired and continue to acquire intangible assets in connection with business combinations. These intangible assets consist primarily of technology associated with currently marketed human therapeutic products and IPR&D product candidates. Discounted cash flow models are typically used to determine the fair values of these intangible assets for purposes of allocating consideration paid to the net assets acquired in a business combination. See Part IV—Note 3, Business combinations, to the Consolidated Financial Statements. These models require the use of significant estimates and assumptions, including, but not limited to:

- determining the timing and expected costs to complete in-process projects taking into account the stage of completion at the acquisition date;
- projecting the probability and timing of obtaining marketing approval from the FDA and other regulatory agencies for product candidates;
- estimating the timing of and future net cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates to calculate the present values of the cash flows.

Significant estimates and assumptions are also required to determine the acquisition date fair values of any contingent consideration obligations incurred in connection with business combinations. In addition, we must revalue these obligations each subsequent reporting period until the related contingencies are resolved and record changes in their fair values in earnings. The acquisition date fair values of contingent consideration obligations incurred or assumed in the acquisitions of businesses were determined using a combination of valuation techniques. Significant estimates and assumptions required for these valuations included, but were not limited to, the probability of achieving regulatory milestones, product sales projections under various scenarios and discount rates used to calculate the present value of the required payments. These estimates and assumptions are required to be updated in order to revalue these contingent consideration obligations each reporting period. Accordingly, subsequent changes in underlying facts and circumstances could result in changes in these estimates and assumptions, which could have a material impact on the estimated future fair values of these obligations. For example, during 2017, we discontinued the internal development of AMG 899 and consequently reduced the related contingent consideration liabilities. See Part IV—Note 16, Fair value measurement, to the Consolidated Financial Statements.

We believe the fair values used to record intangible assets acquired and contingent consideration obligations incurred in connection with business combinations are based upon reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Impairment of long-lived assets

We review the carrying value of our property, plant and equipment and our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows to be generated by the long-lived asset is compared to the carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value.

Indefinite-lived intangible assets, composed of IPR&D projects acquired in a business combination which have not reached technological feasibility or lack regulatory approval at the time of acquisition, are reviewed for impairment annually, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon establishment of technological feasibility or regulatory approval. We determine impairment by comparing the fair value of the asset to its carrying value. If the

asset's carrying value exceeds its fair value, an impairment charge is recorded for the difference and its carrying value is reduced accordingly.

Estimating future cash flows of an IPR&D product candidate for purposes of an impairment analysis requires us to make significant estimates and assumptions regarding the amount and timing of costs to complete the project and the amount, timing and probability of achieving revenues from the completed product similar to how the acquisition date fair value of the project was determined, as described above. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market these products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods which could have a material adverse effect on our results of operations. For example, during 2017, we discontinued the internal development of AMG 899 and consequently recorded an IPR&D asset impairment charge. See Part IV—Note 12, Goodwill and other intangible assets, to the Consolidated Financial Statements.

We believe our estimations of future cash flows used for assessing impairment of long-lived assets are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks that may result from changes in interest rates, foreign currency exchange rates and prices of equity instruments as well as changes in general economic conditions in the countries where we conduct business. To reduce certain of these risks, we enter into various types of foreign currency and interest rate derivative hedging transactions as part of our risk management program. We do not use derivatives for speculative trading purposes.

In the discussion that follows, we have assumed a hypothetical change in interest rates of 100 basis points from those as of December 31, 2017 and 2016. We have also assumed a hypothetical 20% change in foreign currency exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2017 and 2016.

Interest rate sensitive financial instruments

Our portfolio of available-for-sale interest-bearing securities as of December 31, 2017 and 2016, was composed of: U.S. Treasury securities and other government-related debt securities; corporate debt securities; residential mortgage-backed and other mortgage- and asset-backed securities; money market mutual funds; and other short-term interest-bearing securities, composed principally of commercial paper. The fair values of our investment portfolio of interest-bearing securities were $41.2 billion and $37.6 billion as of December 31, 2017 and 2016, respectively. Duration is a sensitivity measure that can be used to approximate the change in the value of a security that will result from a 100 basis point change in interest rates. Applying a duration model, a hypothetical 100 basis point increase in interest rates as of December 31, 2017 and 2016, would have resulted in a reduction in the fair values of these securities of $1.1 billion and $900 million, respectively, on these dates. In addition, a hypothetical 100 basis point decrease in interest rates as of December 31, 2017 and 2016, would not result in a material effect on income in the respective ensuing year.

As of December 31, 2017, we had outstanding debt with a carrying value of $35.3 billion and a fair value of $38.6 billion. As of December 31, 2016, we had outstanding debt with a carrying value of $34.6 billion and a fair value of $36.5 billion. Our outstanding debt was composed primarily of debt with fixed interest rates with variable rate debt having a carrying value of $850 million and $1.5 billion as of December 31, 2017 and 2016, respectively. Changes in interest rates do not affect interest expense on fixed-rate debt. Changes in interest rates would, however, affect the fair values of fixed-rate debt. A hypothetical 100 basis point decrease in interest rates relative to interest rates as of December 31, 2017 and 2016, would have resulted in an increase of $3.3 billion and $3.0 billion, respectively, in the aggregate fair value of our outstanding debt on each of these dates. The analysis for the debt does not consider the impact that hypothetical changes in interest rates would have on the related interest rate swap contracts and cross-currency swap contracts, discussed below.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts which qualified and were designated for accounting purposes as fair value hedges, for certain of our fixed-rate debt. These interest rate swap contracts effectively converted a fixed-rate interest coupon to a floating-rate LIBOR-based coupon over the life of the respective note. Interest rate swap contracts with aggregate notional amounts of $9.45 billion and $6.65 billion were outstanding as of December 31, 2017 and 2016, respectively. A hypothetical 100 basis point

increase in interest rates relative to interest rates as of December 31, 2017 and 2016, would have resulted in reductions in fair values of $420 million and $240 million, respectively, on our interest rate swap contracts on these dates and would not result in a material effect on the related income in the respective ensuing years. The analysis for the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair values of debt that these interest rate sensitive instruments were designed to offset.

As of December 31, 2017 and 2016, we had outstanding cross-currency swap contracts with aggregate notional amounts of $5.6 billion that hedge certain of our foreign-currency denominated debt and related interest payments. These contracts effectively convert interest payments and principal repayment of this debt to U.S. dollars from euros, pounds sterling and Swiss francs and are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates as of December 31, 2017 and 2016, would have resulted in reductions in the fair values of our cross-currency swap contracts of $390 million and $450 million, respectively.

Foreign currency sensitive financial instruments

Our international operations are affected by fluctuations in the value of the U.S. dollar as compared to foreign currencies, predominantly the euro. Increases and decreases in our international product sales from movements in foreign currency exchange rates are offset partially by the corresponding increases or decreases in our international operating expenses. Increases and decreases in our foreign-currency denominated assets from movements in foreign currency exchange rates are offset partially by the corresponding increases or decreases in our foreign-currency denominated liabilities. To further reduce our net exposure to foreign currency exchange rate fluctuations on our results of operations, we enter into foreign currency forward, option and cross-currency swap contracts.

As of December 31, 2017, we had outstanding euro, pound sterling and Swiss franc denominated debt with a principal carrying value and fair value of $6.2 billion and $6.7 billion, respectively. As of December 31, 2016, we had outstanding euro, pound sterling and Swiss franc denominated debt with a principal carrying value and fair value of $5.5 billion and $6.0 billion, respectively. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2017, would have resulted in an increase in fair value of this debt of $1.3 billion on this date and a reduction in income in the ensuing year of $1.2 billion. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2016, would have resulted in an increase in fair value of this debt of $1.2 billion on this date and a reduction in income in the ensuing year of $1.1 billion. The impact on income from these hypothetical changes in foreign currency exchange rates would be substantially offset by the impact such changes would have on related cross-currency swap contracts, which are in place for the majority of the foreign currency denominated debt.

We have cross-currency swap contracts that are designated as cash flow hedges of certain of our debt denominated in euros, pounds sterling and Swiss francs with an aggregate notional amount of $5.6 billion, as of December 31, 2017 and 2016. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates, would have resulted in a reduction in the fair values of these contracts of $1.3 billion and $1.2 billion on these dates, respectively. The impact on income in the ensuing years from these contracts of this hypothetical adverse movement in foreign currency exchange rates would be fully offset by the corresponding hypothetical changes in the carrying amounts of the related hedged debt.

We enter into foreign currency forward and options contracts that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2017, we had open foreign currency forward and options contracts, primarily euro-based, with notional amounts of $4.6 billion and $74 million, respectively. As of December 31, 2016, we had open foreign currency forward and options contracts, primarily euro-based, with notional amounts of $3.4 billion and $608 million, respectively. As of December 31, 2017 and 2016, the fair values of these contracts were a $200 million liability and a $200 million asset, respectively. With regard to foreign currency forward and option contracts that were open as of December 31, 2017, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2017, would have resulted in a reduction in fair value of these contracts of $930 million on this date and, in the ensuing year, a reduction in income of $360 million. With regard to contracts that were open as of December 31, 2016, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2016, would have resulted in a reduction in fair value of these contracts of $650 million on this date and, in the ensuing year, a reduction in income of $300 million. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign currency sensitive instruments were designed to offset.

As of December 31, 2017 and 2016, we had open foreign currency forward contracts with notional amounts of $757 million and $666 million, respectively, that hedged fluctuations of certain assets and liabilities denominated in foreign currencies but were not designated as hedges for accounting purposes. These contracts had no material net unrealized gains or losses as of December 31, 2017 and 2016. With regard to these foreign currency forward contracts that were open as of December 31, 2017 and 2016, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would not have a

material effect on the fair values of these contracts or related income in the respective ensuing years. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on assets and liabilities that these foreign currency sensitive instruments were designed to offset.

Market price sensitive financial instruments

As of December 31, 2017 and 2016, we were also exposed to price risk on equity securities included in our portfolio of investments, which were acquired primarily for the promotion of business and strategic objectives. These investments are generally in small capitalization stocks in the biotechnology industry sector. Price risk relative to our equity investment portfolio as of December 31, 2017 and 2016, was not material.

Counterparty credit risks

Our financial instruments, including derivatives, are subject to counterparty credit risk which we consider as part of the overall fair value measurement. Our financial risk management policy limits derivative transactions by requiring transactions to be with institutions with minimum credit ratings of A- or equivalent by S&P, Moody's or Fitch and requires placing exposure limits on the amount with any individual counterparty. In addition, we have an investment policy that limits investments to certain types of debt and money market instruments issued by institutions primarily with investment-grade credit ratings and places restriction on maturities and concentrations by asset class and issuer.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is incorporated herein by reference to the financial statements and schedule listed in Item 15(a)1 and (a)2 of Part IV and included in this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance Amgen's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2017.

Management determined that, as of December 31, 2017, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States. However, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and reporting.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2017. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our assessment, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

The effectiveness of the Company's internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing below, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2017.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Amgen Inc.

Opinion on Internal Control over Financial Reporting

We have audited Amgen Inc.'s internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Amgen Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Amgen Inc. as of December 31, 2017 and 2016, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 of the Company and our report dated February 13, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Los Angeles, California
February 13, 2018

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about our Directors is incorporated by reference from the section entitled ITEM 1—ELECTION OF DIRECTORS in our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2017 (the Proxy Statement). Information about compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated by reference from the section entitled OTHER MATTERS—Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement. Information about the procedures by which stockholders may recommend nominees for the Board of Directors is incorporated by reference from APPENDIX A—AMGEN INC. BOARD OF DIRECTORS GUIDELINES FOR DIRECTOR QUALIFICATIONS AND EVALUATIONS and OTHER MATTERS—Stockholder Proposals for the 2019 Annual Meeting in our Proxy Statement. Information about our Audit Committee, members of the committee and our Audit Committee financial experts is incorporated by reference from the section entitled CORPORATE GOVERNANCE—Audit Committee in our Proxy Statement. Information about our executive officers is contained in the discussion entitled Item 1. Business—Executive Officers of the Registrant.

Code of Ethics

We maintain a Code of Ethics for CEO and Senior Financial Officers applicable to our principal executive officer, principal financial officer, principal accounting officer or controller, and other persons performing similar functions. To view this code of ethics free of charge, please visit our website at www.amgen.com. (This website address is not intended to function as a hyperlink, and the information contained in our website is not intended to be a part of this filing.) We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics, if any, by posting such information on our website as set forth above.

Item 11. EXECUTIVE COMPENSATION

Information about director and executive compensation is incorporated by reference from the section entitled EXECUTIVE COMPENSATION in our Proxy Statement. Information about compensation committee matters is incorporated by reference from the sections entitled CORPORATE GOVERNANCE—Compensation and Management Development Committee and CORPORATE GOVERNANCE—Compensation Committee Report in our Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table sets forth certain information as of December 31, 2017, concerning the shares of our common stock that may be issued under any form of award granted under our equity compensation plans in effect as of December 31, 2017 (including upon the exercise of options, the vesting of awards of restricted stock units (RSUs), or when performance units are earned, and related dividend equivalents have been granted).

Plan category	(a) Number of securities to be issued upon exercise of outstanding options and rights	(b) Weighted average exercise price outstanding options and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by Amgen security holders:			
Amended and Restated 2009 Equity Incentive Plan[1]	9,842,199	$ 127.10	36,100,581
Amended and Restated 1991 Equity Incentive Plan[2]	23,845	—	—
Amended and Restated Employee Stock Purchase Plan	—	—	4,761,810
Total approved plans	9,866,044	$ 127.10	40,862,391
Equity compensation plan not approved by Amgen security holders:			
Amgen Profit Sharing Plan for Employees in Ireland[3]	—	—	107,908
Total unapproved plans	—	$ —	107,908
Total all plans	9,866,044	$ 127.10	40,970,299

(1) The Amended and Restated 2009 Equity Incentive Plan employs a fungible share counting formula for determining the number of shares available for issuance under the plan. In accordance with this formula, each option or stock appreciation right counts as one share, while each restricted stock unit, performance unit or dividend equivalent counts as 1.9 shares. The number under column (a) represents the actual number of shares issuable under our outstanding awards without giving effect to the fungible share counting formula. The number under column (c) represents the number of shares available for issuance under this plan based on each such available share counting as one share. Commencing with the grants made in April 2012, RSUs and performance units accrue dividend equivalents that are payable in shares only to the extent and when the underlying RSUs vest or underlying performance units have been earned and the related shares are issued to the grantee. The performance units granted under this plan are earned based on the accomplishment of specified performance goals at the end of their respective three-year performance periods; the number of performance units granted represent target performance and the maximum number of units that could be earned based on our performance is 150% of the performance units granted in 2015 and 200% of performance units granted in 2016 and 2017.

As of December 31, 2017, the number of outstanding awards under column (a) includes: (i) 3,963,390 shares issuable upon the exercise of outstanding options with a weighted-average exercise price of $127.10; (ii) 3,664,499 shares issuable upon the vesting of outstanding RSUs (including 177,631 related dividend equivalents); and (iii) 2,214,310 shares subject to outstanding 2015, 2016 and 2017 performance units (including 99,373 related dividend equivalents). The weighted-average exercise price shown in column (b) is for the outstanding options only. The number of available shares under column (c) represents the number of shares that remain available for future issuance under this plan as of December 31, 2017, employing the fungible share formula and presumes the issuance of target shares under the performance units granted in 2015, 2016 and 2017 and related dividend equivalents. The numbers under columns (a) and (c) do not give effect to the additional shares that could be issuable in the event above target on the performance goals under these

outstanding performance units are achieved. Maximum performance under these goals could result in 150% of target shares being awarded for performance units granted in 2015 and 200% of target shares being awarded for performance units granted in 2016 and 2017.

(2) This plan has terminated as to future grants. The number under column (a) with respect to this plan includes 23,845 shares issuable upon the settlement of deferred RSUs (including 3,053 related dividend equivalents).

(3) The Amgen Profit Sharing Plan for Employees in Ireland (the Profit Sharing Plan) was approved by the Board of Directors on July 28, 2011. The Profit Sharing Plan permits eligible employees of the Company's subsidiaries located in Ireland, which participate in the Profit Sharing Plan, to apply a portion of their qualifying bonus and salary to the purchase the Company's common stock on the open market at the market price by a third-party trustee as described in the Profit Sharing Plan.

Security Ownership of Directors and Executive Officers and Certain Beneficial Owners

Information about security ownership of certain beneficial owners and management is incorporated by reference from the sections entitled SECURITY OWNERSHIP OF DIRECTORS AND EXECUTIVE OFFICERS and SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS in our Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information about certain relationships and related transactions and director independence is incorporated by reference from the sections entitled CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS and CORPORATE GOVERNANCE—Director Independence in our Proxy Statement.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information about the fees for professional services rendered by our independent registered public accountants is incorporated by reference from the section entitled AUDIT MATTERS—Independent Registered Public Accountants in our Proxy Statement.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)1. Index to Financial Statements

The following Consolidated Financial Statements are included herein:

	Page number
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Statements of Income for each of the three years in the period ended December 31, 2017	F-2
Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2017	F-3
Consolidated Balance Sheets at December 31, 2017 and 2016	F-4
Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2017	F-5
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2017	F-6
Notes to Consolidated Financial Statements	F-7

(a)2. Index to Financial Statement Schedules

The following Schedule is filed as part of this Annual Report on Form 10-K:

	Page number
II. Valuation and Qualifying Accounts	F-50

All other schedules are omitted because they are not applicable, not required or because the required information is included in the consolidated financial statements or notes thereto.

(a)3. Exhibits

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 13, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)

4.4 First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)

4.5 8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)

4.6 Officer's Certificate of Amgen Inc., dated January 1, 1992, as supplemented by the First Supplemental Indenture, dated February 26, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)

4.7 Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)

4.8 Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)

4.9 Officers' Certificate of Amgen Inc., dated May 30, 2007, including forms of the Company's Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)

4.10 Officers' Certificate of Amgen Inc., dated May 23, 2008, including forms of the Company's 6.15% Senior Notes due 2018 and 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)

4.11 Officers' Certificate of Amgen Inc., dated January 16, 2009, including forms of the Company's 5.70% Senior Notes due 2019 and 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)

4.12 Officers' Certificate of Amgen Inc., dated March 12, 2010, including forms of the Company's 4.50% Senior Notes due 2020 and 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.)

4.13 Officers' Certificate of Amgen Inc., dated September 16, 2010, including forms of the Company's 3.45% Senior Notes due 2020 and 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)

4.14 Officers' Certificate of Amgen Inc., dated June 30, 2011, including forms of the Company's 2.30% Senior Notes due 2016, 4.10% Senior Notes due 2021 and 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)

4.15 Officers' Certificate of Amgen Inc., dated November 10, 2011, including forms of the Company's 1.875% Senior Notes due 2014, 2.50% Senior Notes due 2016, 3.875% Senior Notes due 2021 and 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)

4.16 Officers' Certificate of Amgen Inc., dated December 5, 2011, including forms of the Company's 4.375% Senior Notes due 2018 and 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)

4.17 Officers' Certificate of Amgen Inc., dated May 15, 2012, including forms of the Company's 2.125% Senior Notes due 2017, 3.625% Senior Notes due 2022 and 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)

4.18 Officers' Certificate of Amgen Inc., dated September 13, 2012, including forms of the Company's 2.125% Senior Notes due 2019 and 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)

4.19 Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)

4.20 Officers' Certificate of Amgen Inc., dated May 22, 2014, including forms of the Company's Senior Floating Rate Notes due 2017, Senior Floating Rate Notes due 2019, 1.250% Senior Notes due 2017, 2.200% Senior Notes due 2019 and 3.625% Senior Notes due 2024. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)

4.21 Officer's Certificate of Amgen Inc., dated May 1, 2015, including forms of the Company's 2.125% Senior Notes due 2020, 2.700% Senior Notes due 2022, 3.125% Senior Notes due 2025 and 4.400% Senior Notes due 2045. (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.)

4.22 Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including forms of the Company's 1.250% Senior Notes due 2022 and 2.000% Senior Notes due 2026. (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.)

4.23 Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)

4.24 Terms of the Bonds for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)

4.25	Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.26	Registration Rights Agreement, dated as of June 14, 2016, by and among Amgen Inc., Credit Suisse Securities (USA) LLC, J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Mizuho Securities USA Inc., as lead dealer managers, and Drexel Hamilton, LLC and The Williams Capital Group, L.P., as co-dealer managers. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 1.850% Senior Notes due 2021, 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.28	Officer's Certificate of Amgen Inc., dated as of May 11, 2017, including in forms of the Company's Senior Floating Rate Notes due 2019, Senior Floating Rate Notes due 2020, 1.900% Senior Notes due 2019, 2.200% Senior Notes due 2020 and 2.650% Senior Notes due 2022. (Filed as an exhibit to Form 8-K on May 11, 2017 and incorporated by reference.)
4.29	Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated by reference.)
10.1+	Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
10.2+	First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.)
10.3+	Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)
10.4+*	Form of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 12, 2017.)
10.5+*	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 12, 2017.)
10.6+*	Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.)
10.7+*	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.)
10.8+*	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on October 24, 2017.)
10.9+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.10+*	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on October 24, 2017.)
10.11+*	Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program.
10.12+	Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.13+	

First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)

10.14+ Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.)

10.15+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.16+	First Amendment to the Amgen Inc. Executive Incentive Plan, effective December 13, 2012. (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.)
10.17+	Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.18+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.19+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.20+	Agreement between Amgen Inc. and David W. Meline, effective July 21, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2014 on October 29, 2014 and incorporated herein by reference.)
10.21+	Agreement between Amgen Inc. and Jonathan Graham, dated May 11, 2015. (Filed as an exhibit to Form 10-Q/A for the quarter ended June 30, 2015 on August 6, 2015 and incorporated herein by reference.)
10.22+	Agreement between Amgen Inc. and Lori Johnston, dated October 25, 2016. (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.23	Shareholders' Agreement, dated May 11, 1984, among Amgen, Kirin Brewery Company, Limited and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.24	Amendment No. 1 dated March 19, 1985, Amendment No. 2 dated July 29, 1985 (effective July 1, 1985), and Amendment No. 3, dated December 19, 1985, to the Shareholders' Agreement dated May 11, 1984. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
10.25	Amendment No. 4 dated October 16, 1986 (effective July 1, 1986), Amendment No. 5 dated December 6, 1986 (effective July 1, 1986), Amendment No. 6 dated June 1, 1987, Amendment No. 7 dated July 17, 1987 (effective April 1, 1987), Amendment No. 8 dated May 28, 1993 (effective November 13, 1990), Amendment No. 9 dated December 9, 1994 (effective June 14, 1994), Amendment No. 10 effective March 1, 1996, and Amendment No. 11 effective March 20, 2000 to the Shareholders' Agreement, dated May 11, 1984. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.26	Amendment No. 12 to the Shareholders' Agreement, dated January 31, 2001. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2005 on August 8, 2005 and incorporated herein by reference.)
10.27	Amendment No. 13 to the Shareholders' Agreement, dated June 28, 2007 (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.28	Amendment No. 14 to the Shareholders' Agreement, dated March 26, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2014 on April 30, 2014 and incorporated herein by reference.)
10.29	

Assignment and License Agreement, dated October 16, 1986 (effective July 1, 1986), between Amgen and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)

10.30 G-CSF United States License Agreement, dated June 1, 1987 (effective July 1, 1986), Amendment No. 1, dated October 20, 1988, and Amendment No. 2, dated October 17, 1991 (effective November 13, 1990), between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)

10.31 G-CSF European License Agreement, dated December 30, 1986, between Kirin-Amgen and Amgen, Amendment No. 1 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated June 1, 1987, Amendment No. 2 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated March 15, 1998, Amendment No. 3 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated October 20, 1988, and Amendment No. 4 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated December 29, 1989, between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)

10.32 Amended and Restated Credit Agreement, dated July 30, 2014, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent (Filed as an exhibit to Form 8-K on July 30, 2014 and incorporated herein by reference.)

10.33 Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)

10.34 Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.

10.35 Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)

10.36 Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)

10.37 Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)

10.38 Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)

10.39 Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)

10.40 Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)

10.41 Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)

10.42 Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

10.43	Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.44	Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

10.45	Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
21*	Subsidiaries of the Company
23	Consent of the Independent Registered Public Accounting Firm. The consent is set forth on page 75 of this Annual Report on Form 10-K.
24	Power of Attorney. The Power of Attorney is set forth on page 76 of this Annual Report on Form 10-K.
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

(* = filed herewith)
(** = furnished herewith and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended)
(+ = management contract or compensatory plan or arrangement)

Item 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMGEN INC.
(Registrant)

Date: February 13, 2018

By: /s/ DAVID W. MELINE

David W. Meline
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-8 No. 333-159377) pertaining to the Amgen Inc. 2009 Equity Incentive Plan;

- Registration Statement (Form S-8 No. 33-39183) pertaining to the Amended and Restated Employee Stock Purchase Plan;

- Registration Statements (Form S-8 No. 33-39104, as amended by Form S-8 No. 333-144581 and 333-216719) pertaining to the Amended and Restated Amgen Retirement and Savings Plan (formerly known as the Amgen Retirement and Savings Plan);

- Registration Statements (Form S-8 Nos. 33-47605, 333-144580 and 333-216715) pertaining to the Retirement and Savings Plan for Amgen Manufacturing, Limited (formerly known as the Retirement and Savings Plan for Amgen Manufacturing, Inc.);

- Registration Statements (Form S-8 Nos. 333-81284, 333-177868 and 333-216723) pertaining to the Amgen Nonqualified Deferred Compensation Plan;

- Registration Statement (Form S-3 No. 333-216060) relating to debt securities, common stock, preferred stock, warrants to purchase debt securities, common stock, preferred stock or depositary shares, rights to purchase common stock or preferred stock, securities purchase contracts, securities purchase units and depositary shares of Amgen Inc. and in the related Prospectus; and

- Registration Statement (Form S-8 No. 333-176240) pertaining to the Amgen Profit Sharing Plan for Employees in Ireland;

of our reports dated February 13, 2018, with respect to the consolidated financial statements and schedule of Amgen Inc. and the effectiveness of internal control over financial reporting of Amgen Inc. included in this Annual Report (Form 10-K) of Amgen Inc. for the year ended December 31, 2017.

/s/ Ernst & Young LLP

Los Angeles, California
February 13, 2018

EXHIBIT 24

POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David W. Meline, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming that said attorney-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/S/ ROBERT A. BRADWAY **Robert A. Bradway**	Chairman of the Board, Chief Executive Officer and President, and Director (Principal Executive Officer)	2/13/2018
/S/ DAVID W. MELINE **David W. Meline**	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	2/13/2018
/S/ WANDA M. AUSTIN **Wanda M. Austin**	Director	2/13/2018
/S/ DAVID BALTIMORE **David Baltimore**	Director	2/13/2018
/S/ FRANÇOIS DE CARBONNEL **François de Carbonnel**	Director	2/13/2018
/S/ ROBERT A. ECKERT **Robert A. Eckert**	Director	2/13/2018
/S/ GREG C. GARLAND **Greg C. Garland**	Director	2/13/2018
/S/ FRED HASSAN **Fred Hassan**	Director	2/13/2018
/S/ REBECCA M. HENDERSON **Rebecca M. Henderson**	Director	2/13/2018
/S/ FRANK C. HERRINGER **Frank C. Herringer**	Director	2/13/2018
/S/ CHARLES M. HOLLEY, JR. **Charles M. Holley, Jr.**	Director	2/13/2018
/S/ TYLER JACKS **Tyler Jacks**	Director	2/13/2018
/S/ ELLEN J. KULLMAN **Ellen J. Kullman**	Director	2/13/2018
/S/ RONALD D. SUGAR **Ronald D. Sugar**	Director	2/13/2018
/S/ R. SANDERS WILLIAMS	Director	2/13/2018

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Amgen Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amgen Inc. (the Company) as of December 31, 2017 and 2016, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2017 and 2016, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 13, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1980.

Los Angeles, California

February 13, 2018

AMGEN INC.

CONSOLIDATED STATEMENTS OF INCOME

Years ended December 31, 2017, 2016 and 2015

(In millions, except per share data)

	2017	2016	2015
Revenues:			
Product sales	$ 21,795	$ 21,892	$ 20,944
Other revenues	1,054	1,099	718
Total revenues	22,849	22,991	21,662
Operating expenses:			
Cost of sales	4,069	4,162	4,227
Research and development	3,562	3,840	4,070
Selling, general and administrative	4,870	5,062	4,846
Other	375	133	49
Total operating expenses	12,876	13,197	13,192
Operating income	9,973	9,794	8,470
Interest expense, net	1,304	1,260	1,095
Interest and other income, net	928	629	603
Income before income taxes	9,597	9,163	7,978
Provision for income taxes	7,618	1,441	1,039
Net income	$ 1,979	$ 7,722	$ 6,939
Earnings per share:			
Basic	$ 2.71	$ 10.32	$ 9.15
Diluted	$ 2.69	$ 10.24	$ 9.06
Shares used in the calculation of earnings per share:			
Basic	731	748	758
Diluted	735	754	766

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Years ended December 31, 2017, 2016 and 2015

(In millions)

	2017	2016	2015
Net income	$ 1,979	$ 7,722	$ 6,939
Other comprehensive (loss) income, net of reclassification adjustments and taxes:			
Foreign currency translation gains (losses)	81	(99)	(247)
Effective portion of cash flow hedges	(288)	(15)	7
Net unrealized (losses) gains on available-for-sale securities	(6)	122	(241)
Other	5	1	9
Other comprehensive (loss) income, net of tax	(208)	9	(472)
Comprehensive income	$ 1,771	$ 7,731	$ 6,467

See accompanying notes.

AMGEN INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2017 and 2016

(In millions, except per share data)

	2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,800	$ 3,241
Marketable securities	37,878	34,844
Trade receivables, net	3,237	3,165
Inventories	2,834	2,745
Other current assets	1,727	2,015
Total current assets	49,476	46,010
Property, plant and equipment, net	4,989	4,961
Intangible assets, net	8,609	10,279
Goodwill	14,761	14,751
Other assets	2,119	1,625
Total assets	$ 79,954	$ 77,626
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,352	$ 917
Accrued liabilities	6,516	5,884
Short-term borrowings and current portion of long-term debt	1,152	4,403
Total current liabilities	9,020	11,204
Long-term debt	34,190	30,193
Long-term deferred tax liabilities	1,166	2,436
Long-term tax liabilities	9,099	2,419
Other noncurrent liabilities	1,238	1,499
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value per share; 2,750.0 shares authorized; outstanding—722.2 shares in 2017 and 738.2 shares in 2016	30,992	30,784
Accumulated deficit	(5,072)	(438)
Accumulated other comprehensive loss	(679)	(471)
Total stockholders' equity	25,241	29,875
Total liabilities and stockholders' equity	$ 79,954	$ 77,626

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended December 31, 2017, 2016 and 2015

(In millions)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance at December 31, 2014	760.4	$ 30,410	$ (4,624)	$ (8)	$ 25,778
Net income	—	—	6,939	—	6,939
Other comprehensive loss, net of tax	—	—	—	(472)	(472)
Dividends	—	—	(2,548)	—	(2,548)
Issuance of common stock in connection with the Company's equity award programs	5.6	82	—	—	82
Stock-based compensation expense	—	319	—	—	319
Tax impact related to employee stock-based compensation expense	—	(162)	—	—	(162)
Repurchases of common stock	(12.0)	—	(1,853)	—	(1,853)
Balance at December 31, 2015	754.0	30,649	(2,086)	(480)	28,083
Net income	—	—	7,722	—	7,722
Other comprehensive income, net of tax	—	—	—	9	9
Dividends	—	—	(3,120)	—	(3,120)
Issuance of common stock in connection with the Company's equity award programs	3.9	55	—	—	55
Stock-based compensation expense	—	342	—	—	342
Tax impact related to employee stock-based compensation expense	—	(262)	73	—	(189)
Repurchases of common stock	(19.7)	—	(3,027)	—	(3,027)
Balance at December 31, 2016	738.2	30,784	(438)	(471)	29,875
Net income	—	—	1,979	—	1,979
Other comprehensive loss, net of tax	—	—	—	(208)	(208)
Dividends	—	—	(3,487)	—	(3,487)
Issuance of common stock in connection with the Company's equity award programs	2.5	52	—	—	52
Stock-based compensation expense	—	347	—	—	347
Tax impact related to employee stock-based compensation expense	—	(191)	—	—	(191)
Repurchases of common stock	(18.5)	—	(3,126)	—	(3,126)
Balance at December 31, 2017	722.2	$ 30,992	$ (5,072)	$ (679)	$ 25,241

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2017, 2016 and 2015

(In millions)

	2017	2016	2015
Cash flows from operating activities:			
Net income	$ 1,979	$ 7,722	$ 6,939
Depreciation and amortization	1,955	2,105	2,108
Stock-based compensation expense	329	311	322
Deferred income taxes	(1,330)	183	(607)
Other items, net	334	32	(146)
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	(58)	(214)	(420)
Inventories	133	(80)	481
Other assets	(24)	(128)	155
Accounts payable	424	(44)	(12)
Accrued income taxes, net	523	(301)	509
Long-term tax liability	6,681	445	409
Other liabilities	231	323	(7)
Net cash provided by operating activities	11,177	10,354	9,731
Cash flows from investing activities:			
Purchases of property, plant and equipment	(664)	(738)	(594)
Cash paid for acquisitions, net of cash acquired	(19)	—	(359)
Purchases of marketable securities	(33,607)	(28,094)	(25,977)
Proceeds from sales of marketable securities	24,240	17,958	18,029
Proceeds from maturities of marketable securities	6,174	2,459	3,527
Proceeds from sales of property, plant and equipment	11	78	274
Other	(159)	(321)	(447)
Net cash used in investing activities	(4,024)	(8,658)	(5,547)
Cash flows from financing activities:			
Net proceeds from issuance of debt	4,476	7,318	3,465
Repayment of debt	(4,405)	(3,725)	(2,400)
Repurchases of common stock	(3,160)	(2,965)	(1,867)
Dividends paid	(3,365)	(2,998)	(2,396)
Settlement of contingent consideration obligations	—	—	(253)
Withholding taxes arising from shares withheld for share-based payments	(191)	(260)	(401)
Other	51	31	81
Net cash used in financing activities	(6,594)	(2,599)	(3,771)
Increase (decrease) in cash and cash equivalents	559	(903)	413
Cash and cash equivalents at beginning of year	3,241	4,144	3,731
Cash and cash equivalents at end of year	$ 3,800	$ 3,241	$ 4,144

See accompanying notes.

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2017

1. Summary of significant accounting policies

Business

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. We operate in one business segment: human therapeutics.

Principles of consolidation

The consolidated financial statements include the accounts of Amgen as well as its majority-owned subsidiaries. We do not have any significant interests in any variable interest entities. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Product sales

Sales of our products are recognized when shipped and title and risk of loss have passed. Product sales are recorded net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns. Taxes collected from customers and remitted to government authorities related to the sales of the Company's products, primarily in Europe, are excluded from revenues.

Other revenues

Other revenues consist primarily of royalty income and corporate partner revenues. Royalties from licensees are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectibility is reasonably assured. Royalty estimates are made in advance of amounts collected using historical and forecasted trends. Corporate partner revenues are composed mainly of license fees and milestones earned, our share of commercial profits generated from collaborations and amounts earned for certain research and development (R&D) services performed for others, including Kirin-Amgen, Inc. (K-A), which are recognized as the R&D services are performed. See Multiple-deliverable revenue arrangements, discussed below, Note 7, Collaborations, and Note 8, Related party transactions.

Multiple-deliverable revenue arrangements

From time to time, we enter into arrangements for the R&D, manufacture and/or commercialization of products and product candidates. These arrangements may require us to deliver various rights, services and/or goods across the entire life cycle of a product or product candidate, including (i) intellectual property rights/licenses; (ii) R&D services; (iii) manufacturing services; and/or (iv) commercialization services. The underlying terms of these arrangements generally provide for consideration to Amgen in the form of non-refundable upfront license payments, R&D and commercial performance milestone payments, cost sharing and/or royalty payments.

In arrangements involving the delivery of more than one element, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. For Amgen, this determination is generally based on whether the deliverable has "stand-alone value" to the customer. The arrangement's consideration that is fixed and determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value; (ii) third-party evidence of selling price; and (iii) best estimate of selling price (BESP). The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Consideration associated with at-risk substantive performance milestones is recognized as revenue upon the achievement of the related milestone, as defined in the respective contracts.

Research and development costs

R&D costs are expensed as incurred and include primarily salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems' costs and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs and cost recoveries associated with third-party R&D arrangements, including upfront fees and milestones paid to third parties in connection with technologies which had not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 7, Collaborations, and Note 8, Related party transactions.

Selling, general and administrative costs

Selling, general and administrative (SG&A) costs are composed primarily of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses; the U.S. healthcare reform federal excise fee on Branded Prescription Pharmaceutical Manufacturers and Importers; and other general and administrative costs. Advertising costs are expensed as incurred and were $620 million, $489 million and $346 million during the years ended December 31, 2017, 2016 and 2015, respectively. SG&A expenses also include costs and cost recoveries associated with marketing and promotion efforts under certain collaborative arrangements. Net payment or reimbursement of SG&A costs is recognized when the obligations are incurred or we become entitled to the cost recovery. See Note 7, Collaborations.

Stock-based compensation

We have stock-based compensation plans under which various types of equity-based awards are granted, including restricted stock units (RSUs), performance units and stock options. The fair values of RSUs and stock option awards, which are subject only to service conditions with graded vesting, are recognized as compensation expense, generally on a straight-line basis over the service period, net of estimated forfeitures. The fair values of performance unit awards are recognized as compensation expense, generally on a straight-line basis from the grant date to the end of the performance period. See Note 4, Stock-based compensation.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates available in the various jurisdictions in which we operate. Significant judgment is required in determining our provision for income taxes and income tax assets and liabilities, including evaluating uncertainties in the application of accounting principles and complex tax laws. Deferred income taxes are recorded for the expected tax consequences of temporary differences between the bases of assets and liabilities, as well as for loss and tax credit carryforwards for financial reporting purposes and amounts recognized for income tax purposes. We record a valuation allowance to reduce our deferred tax assets to the amount of future tax benefit that is more likely than not to be realized.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits (UTBs) is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense.

On December 22, 2017, the Securities and Exchange Commission (SEC) staff issued Staff Accounting Bulletin No. 118 (SAB 118) to address the accounting implications of the U.S. federal tax reform enacted on December 22, 2017. SAB 118 allows a company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. See Note 5, Income taxes.

Business combinations

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method, assets acquired, including in-process research and development (IPR&D) projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as

goodwill. Contingent consideration obligations incurred in connection with a business combination (including the assumption of an acquiree's liability arising from a business combination it consummated prior to our acquisition) are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent

reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in earnings. See Note 3, Business combinations, and Note 16, Fair value measurement.

Cash equivalents

We consider cash equivalents to be only those investments which are highly liquid, readily convertible to cash and which mature within three months from the date of purchase.

Available-for-sale investments

We consider our investment portfolio available-for-sale and, accordingly, these investments are recorded at fair value with unrealized gains and losses generally recorded in Accumulated other comprehensive income (loss) (AOCI). Investments with maturities beyond one year may be classified as short-term marketable securities in the Consolidated Balance Sheets due to their highly liquid nature and because they represent the Company's investments that are available for current operations. See Note 9, Available-for-sale investments, and Note 16, Fair value measurement.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner that approximates the first-in, first-out method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. See Note 10, Inventories.

Derivatives

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Consolidated Balance Sheets. The accounting for changes in the fair value of a derivative instrument depends upon whether the derivative has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of hedging relationship. For derivatives formally designated as hedges, we assess both at inception and quarterly thereafter, whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item. Our derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings. See Note 16, Fair value measurement, and Note 17, Derivative instruments.

Property, plant and equipment, net

Property, plant and equipment is recorded at historical cost, net of accumulated depreciation, amortization and, if applicable, impairment charges. We review our property, plant and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Depreciation is provided over the assets' useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms. See Note 11, Property, plant and equipment.

Goodwill and other intangible assets

Finite-lived intangible assets are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is provided over their estimated useful lives on a straight-line basis or the pattern in which economic benefits are consumed, if reliably determinable. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note 12, Goodwill and other intangible assets.

The fair values of IPR&D projects acquired in a business combination which are not complete are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related R&D efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written-off immediately. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market the resulting products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods.

Capitalized IPR&D projects are tested for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. We consider various factors for potential

impairment, including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays in obtaining marketing

approval, the inability to bring a product to market and the introduction or advancement of competitors' products could result in partial or full impairment of the related intangible assets.

We perform an impairment test of goodwill annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. To date, an impairment of goodwill has not been recorded. See Note 12, Goodwill and other intangible assets.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings and other matters such as intellectual property disputes, contractual disputes, governmental investigations and class action suits which are complex in nature and have outcomes that are difficult to predict. Certain of these proceedings are discussed in Note 18, Contingencies and commitments. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We consider all relevant factors when making assessments regarding these contingencies.

Foreign currency translation

The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating net assets of these subsidiaries at changing rates are recognized in AOCI. The earnings of these subsidiaries are translated into U.S. dollars using average exchange rates.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB has subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards are effective for interim and annual periods beginning on January 1, 2018. The new standards are required to be adopted using either a full-retrospective or a modified-retrospective approach. We will adopt these standards using the modified-retrospective approach beginning in 2018. We have completed our impact assessment and do not anticipate a material impact to Total revenues in our Consolidated Statements of Income, accounting policies, business processes, internal controls or disclosures.

In January 2016, the FASB issued a new accounting standard that amends the accounting and disclosures of financial instruments, including a provision requiring that equity investments (except for investments accounted for under the equity method of accounting) be measured at fair value, with changes in fair value recognized in current earnings. The new standard is effective for interim and annual periods beginning on January 1, 2018. With the exception of equity investments currently being accounted for at cost, adjustments are applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. The new standard will be applied prospectively to investments currently accounted for at cost which had a carrying value of $95 million as of December 31, 2017. Upon adoption, on January 1, 2018, we will record an immaterial adjustment to Retained earnings from AOCI, which represents the net unrealized gain on all equity investments with a readily determinable fair value as of December 31, 2017. The impact that this new standard will have on our Consolidated Statements of Income after adoption will depend on the changes in fair values of equity securities in our portfolio in the future. See Note 9, Available-for-sale investments for the fair value of all equity securities as of December 31, 2017.

In February 2016, the FASB issued a new accounting standard that amends the guidance for the accounting and disclosure of leases. This new standard requires that lessees recognize the assets and liabilities that arise from leases on the balance sheet, including leases classified as operating leases under current GAAP, and disclose qualitative and quantitative information about leasing arrangements. The new standard requires a modified-retrospective approach to adoption and is effective for interim and annual periods beginning on January 1, 2019, but may be adopted earlier. We expect to adopt this standard beginning in 2019. We do not expect that this standard will have a material impact on our Consolidated Statements of Income, but we do expect that upon adoption, this standard will have a material impact on our assets and liabilities on our Consolidated Balance Sheets. The primary effect of adoption will be the requirement to record right-of-use assets and corresponding lease obligations for current operating leases. In addition, the standard will require that we update our systems, processes and controls we use to track, record and account for our lease portfolio. We have selected a lease accounting information system and engaged third-party consultants to provide system implementation services. System readiness, including implementation and

functionality of software procured from third-party providers, is essential to enable the preparation of financial information required for this standard.

In June 2016, the FASB issued a new accounting standard that amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. Accordingly, these financial assets will be presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The new standard is effective for interim and annual periods beginning on January 1, 2020, but may be adopted earlier, beginning on January 1, 2019. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. We are currently evaluating the impact that this new standard will have on our consolidated financial statements.

In October 2016, the FASB issued a new accounting standard that amends the income tax accounting guidance for intra-entity transfers of assets other than inventory. The new standard requires that entities recognize the income tax consequences of an intercompany transfer of an asset, other than inventory, in the period the transfer occurs. The current exception to defer the recognition of any tax impact on intercompany transfers of inventory until the inventory is sold to a third party remains unaffected. The new standard is effective for interim and annual periods beginning on January 1, 2018. The standard will be applied prospectively to any transaction occurring on or after the adoption date. We have completed our impact assessment and do not anticipate a material impact on our consolidated financial statements.

In January 2017, the FASB issued a new accounting standard that changes the definition of a business to assist entities with the evaluation of when a set of assets acquired or disposed of should be considered a business. The new standard requires that an entity evaluate whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets; if so, the set of assets would not be considered a business. The new standard also requires that a business include at least one substantive process and narrows the definition of outputs. The new standard will be applied prospectively and is effective for interim and annual periods beginning on January 1, 2018. Adoption of this new standard may result in more transactions being accounted for as asset acquisitions versus business combinations; however, the impact on our consolidated financial statements will depend on the facts and circumstances of future transactions.

2. Restructuring

In 2014, we initiated a restructuring plan to invest in continuing innovation and the launch of our new pipeline molecules, while improving our cost structure. As part of the plan, we have closed facilities in Washington state and Colorado and are reducing the number of buildings we occupy at our headquarters in Thousand Oaks, California, as well as at other locations.

We estimate that we will incur $825 million to $900 million of pre-tax charges in connection with our restructuring, including: (i) separation and other headcount-related costs of $560 million to $600 million with respect to staff reductions and (ii) asset-related charges of $265 million to $300 million that consist primarily of asset impairments, accelerated depreciation and other related costs resulting from the consolidation of our worldwide facilities. Through December 31, 2017, we have incurred $558 million of separation and other headcount-related costs and $239 million of net asset-related charges. In order to support our ongoing transformation and process improvement efforts, we expect that we will incur most of the remaining costs in 2018.

The charges recorded during the years ended December 31, 2017 and 2016 were not material for all types of activities presented below. The following tables summarize charges recorded related to the restructuring plan by type of activity and the locations recognized within the Consolidated Statements of Income (in millions):

	Year ended December 31, 2015				
	Separation costs	Asset impairments/ disposals	Accelerated depreciation	Other	Total
Cost of sales	$ —	$ —	$ 50	$ 2	$ 52
Research and development	—	—	36	28	64
Selling, general and administrative	—	—	14	42	56
Other	49	(111)	—	4	(58)
Total	$ 49	$ (111)	$ 100	$ 76	$ 114

	Year ended December 31, 2014				
	Separation costs	Asset impairments	Accelerated depreciation	Other	Total
Cost of sales	$ —	$ 81	$ 23	$ —	$ 104
Research and development	—	—	28	21	49
Selling, general and administrative	—	—	4	5	9
Other	377	6	—	13	396
Total	$ 377	$ 87	$ 55	$ 39	$ 558

We recognized asset impairment and accelerated depreciation charges in connection with our decision to exit Boulder and Longmont, Colorado, and Bothell and Seattle, Washington, and in connection with the consolidation of facilities in Thousand Oaks, California. The decision to close these manufacturing and R&D facilities was based principally on optimizing the utilization of our sites in the United States, which includes an expansion of our presence in the key U.S. biotechnology hubs of South San Francisco, California, and Cambridge, Massachusetts. During the year ended December 31, 2015, we recognized gains from the sale of assets related to these site closures.

The following table summarizes the expenses (excluding non-cash charges) and payments related to the restructuring plan (in millions):

	Years ended December 31,		
	Separation costs	Other	Total
Restructuring liabilities as of December 31, 2013	$ —	$ —	$ —
Expense	353	32	385
Payments	(132)	(9)	(141)
Restructuring liabilities as of December 31, 2014	221	23	244
Expense	52	80	132
Payments	(178)	(80)	(258)
Restructuring liabilities as of December 31, 2015	95	23	118
Expense	6	13	19
Payments	(90)	(27)	(117)
Restructuring liabilities as of December 31, 2016	11	9	20
Expense	72	7	79
Payments	(20)	$ (11)	(31)
Restructuring liabilities as of December 31, 2017	$ 63	$ 5	$ 68

3. Business combinations

Dezima Pharma B.V.

In 2015, we acquired all of the outstanding stock of Dezima Pharma B.V. (Dezima) whose lead molecule is AMG 899 (formerly TA-8995), an oral, once-daily cholesteryl ester transfer protein inhibitor that had completed certain phase 2 trials. The aggregate acquisition date consideration to acquire Dezima was $410 million, including $110 million for the fair value of contingent consideration obligations related to the development of AMG 899. The fair values of assets acquired and liabilities assumed primarily included an IPR&D asset of $400 million, goodwill of $108 million (which is not deductible for tax purposes) and deferred tax liabilities of $100 million. The goodwill was attributable primarily to the expected synergies and other benefits that we believed would result from expanding our cardiovascular portfolio with AMG 899; and the deferred tax consequences of acquired IPR&D recorded for financial statement purposes.

During the year ended December 31, 2017, we decided to discontinue the internal development of AMG 899, resulting in an impairment charge of $400 million for the IPR&D asset and the release of the then fair value of the related contingent consideration liabilities of $116 million. See Note 16, Fair value measurement.

4. Stock-based compensation

Our Amended and Restated 2009 Equity Incentive Plan (the Amended 2009 Plan) authorizes for issuance, shares of our common stock pursuant to grants of equity-based awards, including RSUs, stock options and performance units to employees of Amgen, its subsidiaries and non-employee members of our Board of Directors. The pool of shares available under the Amended 2009 Plan is reduced by one share for each stock option granted and by 1.9 shares for other types of awards granted, including RSUs and performance units (full-value awards). In general, if any shares subject to an award granted under the Amended 2009 Plan expire, or are forfeited, terminated or canceled without the issuance of shares, the shares subject to such awards are added back into the authorized pool on the same basis that they were removed. In addition, under the Amended 2009 Plan, shares withheld to pay for minimum statutory tax obligations with respect to full value awards are added back into the authorized pool on the basis of 1.9 shares. As of December 31, 2017, the Amended 2009 Plan provides for future grants and/or issuances of up to 36 million shares of our common stock. Stock-based awards under our employee compensation plans are made with newly issued shares reserved for this purpose.

The following table reflects the components of stock-based compensation expense recognized in our Consolidated Statements of Income (in millions):

	Years ended December 31,		
	2017	2016	2015
RSUs	$ 174	$ 177	$ 190
Performance units	133	123	132
Stock options	22	11	—
Total stock-based compensation expense, pretax	329	311	322
Tax benefit from stock-based compensation expense	(118)	(112)	(120)
Total stock-based compensation expense, net of tax	$ 211	$ 199	$ 202

Restricted stock units and stock options

Eligible employees generally receive an annual grant of RSUs and, for certain executive level employees, stock options, with the size and type of award generally determined by the employee's salary grade and performance level. In 2016, we reinstated the practice of granting stock options to eligible employees annually, which had been suspended from 2012 through 2015. In addition, certain management and professional-level employees typically receive RSU grants upon commencement of employment. Non-employee members of our Board of Directors also receive an annual grant of RSUs.

Our RSU and stock option grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including upon death, disability, termination in connection with a change in control and the retirement of employees who meet certain service and/or age requirements. RSUs and stock options generally vest in equal amounts on the second, third and fourth anniversaries of the grant date. RSUs

accrue dividend equivalents which are typically payable in shares only when and to the extent the underlying RSUs vest and are issued to the recipient.

Restricted stock units

The grant date fair value of an RSU equals the closing price of our common stock on the grant date, as RSUs accrue dividend equivalents during their vesting period. The weighted-average grant date fair values of RSUs granted during the years ended

December 31, 2017, 2016 and 2015 were $163.99, $156.76 and $166.74, respectively. The following table summarizes information regarding our RSUs:

	Year ended December 31, 2017	
	Units (in millions)	Weighted-average grant date fair value
Balance nonvested at December 31, 2016	3.9	$ 141.07
Granted	1.3	$ 163.99
Vested	(1.5)	$ 125.32
Forfeited	(0.3)	$ 149.79
Balance nonvested at December 31, 2017	3.4	$ 155.11

The total grant date fair values of RSUs that vested during the years ended December 31, 2017, 2016 and 2015, were $182 million, $193 million and $206 million, respectively.

As of December 31, 2017, there was $304 million of unrecognized compensation cost related to nonvested RSU awards, which is expected to be recognized over a weighted-average period of 1.8 years.

Stock options

The exercise price for stock options is set as the closing price of our common stock on the grant date and the related number of shares granted is fixed at that point in time. Awards expire 10 years from the date of grant. We use a Black-Scholes option valuation model to estimate the grant date fair value of stock options. The weighted-average assumptions used in the option valuation model and the resulting weighted-average grant date fair values of stock options granted were as follows:

	Years ended December 31,	
	2017	2016
Closing price of our common stock on grant date	$ 162.60	$ 156.35
Expected volatility (average of implied and historical volatility)	22.7%	24.3%
Expected life (in years)	5.8	5.8
Risk-free interest rate	2.1%	1.5%
Expected dividend yield	2.8%	2.6%
Fair value of stock options granted	$ 27.54	$ 27.55

The following table summarizes information regarding our stock options:

	Year ended December 31, 2017			
	Options (in millions)	Weighted-average exercise price	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in millions)
Balance unexercised at December 31, 2016	3.1	$ 100.21		
Granted	1.5	$ 162.60		
Exercised	(0.5)	$ 57.24		
Expired/forfeited	(0.1)	$ 159.13		
Balance unexercised at December 31, 2017	4.0	$ 127.08	6.9	$ 186
Vested or expected to vest at December 31, 2017	3.7	$ 124.84	6.8	$ 182
Exercisable at December 31, 2017	1.3	$ 58.23	2.8	$ 147

The total intrinsic values of options exercised during the years ended December 31, 2017, 2016 and 2015, were $60 million, $102 million and $150 million, respectively. The actual tax benefits realized from tax deductions from option exercises during the years ended December 31, 2017, 2016 and 2015, were $21 million, $37 million and $55 million, respectively.

Performance units

Certain management-level employees also receive annual grants of performance units, which give the recipient the right to receive common stock that is contingent upon achievement of specified pre-established goals over the performance period, which is generally three years. The performance goals for the units granted during the years ended December 31, 2017, 2016 and 2015, which are accounted for as equity awards, are based upon Amgen's stockholder return compared with a comparator group of companies, which are considered market conditions and are reflected in the grant date fair values of the units, and for units granted during the years ended December 31, 2017 and 2016, Amgen's standalone financial performance measures, which are considered performance conditions. The expense recognized for awards granted during the years ended December 31, 2017 and 2016 are based on the grant date fair value of a unit multiplied by the number of units expected to be earned with respect to the performance conditions, net of estimated forfeitures. The expense recognized for the awards granted during the year ended December 31, 2015 was based on the grant date fair value of a unit multiplied by the number of units granted, net of estimated forfeitures. Depending on the outcome of these performance goals, a recipient may ultimately earn a number of units greater or less than the number of units granted. Shares of our common stock are issued on a one-for-one basis for each performance unit earned. In general, performance unit awards vest at the end of the performance period. The performance award program provides for accelerated or continued vesting in certain circumstances as defined in the plan, including upon death, disability, a change in control and retirement of employees who meet certain service and/or age requirements. Performance units accrue dividend equivalents which are typically payable in shares only when and to the extent the underlying performance units vest and are issued to the recipient, including with respect to market and performance conditions that affect the number of performance units earned.

We use a payout simulation model to estimate the grant date fair value of performance units. The weighted-average assumptions used in this model and the resulting weighted-average grant date fair values of performance units granted were as follows:

	Years ended December 31,		
	2017	2016	2015
Closing price of our common stock on grant date	$ 162.60	$ 156.35	$ 164.26
Volatility	25.9%	25.8%	24.3%
Risk-free interest rate	1.4%	0.9%	0.8%
Fair value of units granted	$ 178.87	$ 170.56	$ 182.55

The payout simulation model assumes correlations of returns of the stock prices of our common stock and the common stocks of the comparator groups of companies and stock price volatilities of the comparator groups of companies.

As of December 31, 2017 and 2016, 2.2 million and 2.8 million performance units were outstanding with weighted-average grant date fair values of $177.16 and $144.43 per unit, respectively. During the year ended December 31, 2017, 0.8 million performance units with a weighted-average grant date fair value of $178.87 were granted and 0.1 million performance units with a weighted-average grant date fair value of $179.58 were forfeited.

The total fair values of performance units that vested during the years ended December 31, 2017 and 2016 were $219 million and $347 million, respectively, based upon the number of performance units earned multiplied by the closing stock price of our common stock on the last day of the performance period. No performance units vested during the year ended December 31, 2015.

As of December 31, 2017, there was $144 million of unrecognized compensation cost that is expected to be recognized over a weighted-average period of 1 year.

5. Income taxes

On December 22, 2017, the United States enacted major tax reform legislation, Public Law No. 115-97, commonly referred to as the Tax Cuts and Jobs Act (2017 Tax Act). The 2017 Tax Act imposes a repatriation tax on

accumulated earnings of foreign subsidiaries, implements a territorial tax system together with a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. On December 22, 2017, the SEC staff issued SAB 118 that allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We currently are analyzing the 2017

Tax Act, and in certain areas, have made reasonable estimates of the effects on our consolidated financial statements and tax disclosures, including the amount of the repatriation tax and changes to our existing deferred tax balances.

The repatriation tax is based primarily on our accumulated foreign earnings and profits that we previously deferred from U.S. income taxes. We recorded an estimated amount for our repatriation tax liability of $7.3 billion as of December 31, 2017. See Note 18, Contingencies and commitments. We no longer reinvest our undistributed earnings of our foreign operations indefinitely outside the United States. In addition, we remeasured certain net deferred and other tax liabilities based on the tax rates at which they are expected to reverse in the future. The estimated amount recorded related to the remeasurement of these balances was a net benefit of $1.2 billion. The net estimated impact of the 2017 Tax Act is $6.1 billion.

We consider the key estimates on the repatriation tax, net deferred tax remeasurement and the impact on our unrealized tax benefits to be incomplete due to our continuing analysis of final year-end data and tax positions. Our analysis could affect the measurement of these balances and give rise to new deferred and other tax assets and liabilities. Since the 2017 Tax Act was passed late in the fourth quarter of 2017, and further guidance and accounting interpretation is expected over the next 12 months, our review is still pending. We expect to complete our analysis within the measurement period.

Income before income taxes included the following (in millions):

	Years ended December 31,		
	2017	2016	2015
Domestic	$ 4,436	$ 4,478	$ 3,532
Foreign	5,161	4,685	4,446
Total income before income taxes	$ 9,597	$ 9,163	$ 7,978

The provision for income taxes included the following (in millions):

	Years ended December 31,		
	2017	2016	2015
Current provision:			
Federal	$ 8,615	$ 984	$ 1,129
State	5	65	40
Foreign	275	176	272
Total current provision	8,895	1,225	1,441
Deferred (benefit) provision:			
Federal	(1,120)	372	(290)
State	—	(69)	(78)
Foreign	(157)	(87)	(34)
Total deferred (benefit) provision	(1,277)	216	(402)
Total provision for income taxes	$ 7,618	$ 1,441	$ 1,039

Deferred income taxes reflect the tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards and the tax effects of net operating loss (NOL) carryforwards.

Significant components of our deferred tax assets and liabilities were as follows (in millions):

	December 31,	
	2017	2016
Deferred income tax assets:		
NOL and credit carryforwards	$ 812	$ 688
Accrued expenses	362	562
Expenses capitalized for tax	155	255
Stock-based compensation	99	167
Other	154	117
Total deferred income tax assets	1,582	1,789
Valuation allowance	(497)	(381)
Net deferred income tax assets	1,085	1,408
Deferred income tax liabilities:		
Acquired intangible assets	(1,748)	(3,139)
Debt	(184)	(345)
Other	(240)	(307)
Total deferred income tax liabilities	(2,172)	(3,791)
Total deferred income taxes, net	$ (1,087)	$ (2,383)

Valuation allowances are provided to reduce the amounts of our deferred tax assets to an amount that is more likely than not to be realized based on an assessment of positive and negative evidence, including estimates of future taxable income necessary to realize future deductible amounts.

The valuation allowance increased in 2017 due primarily to the Company's expectation that some state R&D credits and foreign NOLs will not be utilized. This increase was offset partially by the release of state R&D credits projected to be utilized in 2018 related to the repatriation tax on foreign earnings. The valuation allowance increased in 2016 due primarily to the Company's expectation that some state R&D credits will not be utilized. This increase was offset partially by valuation allowance releases due to sufficient positive evidence to conclude that it is more likely than not that certain foreign NOL carryforwards are realizable.

As of December 31, 2017, we had $20 million of federal tax credit carryforwards available to reduce future federal income taxes and have provided no valuation allowance for those federal tax credit carryforwards. The federal tax credit carryforwards expire between 2026 and 2035. We had $524 million of state tax credit carryforwards available to reduce future state income taxes and have provided a valuation allowance for $392 million of those state tax credit carryforwards. The state credits for which no valuation allowance has been provided will begin to expire in 2022.

As of December 31, 2017, we had $146 million of NOL carryforwards available to reduce future federal income taxes and have provided a valuation allowance for $6 million of those federal NOL carryforwards. The federal NOL carryforwards, for which no valuation allowance has been provided, expire between 2020 and 2035. We had $425 million of NOL carryforwards available to reduce future state income taxes and have provided a valuation allowance for $400 million of those state NOL carryforwards. The state NOLs for which no valuation allowance has been provided expire between 2018 and 2032. We had $2.0 billion of NOL carryforwards available to reduce future foreign income taxes and have provided a valuation allowance for $819 million of those foreign NOL carryforwards. For the foreign NOLs with no valuation allowance provided, $678 million has no expiry; and the remainder will expire starting in 2018.

The reconciliations of the total gross amounts of UTBs (excluding interest, penalties, foreign tax credits and the federal tax benefit of state taxes related to UTBs) were as follows (in millions):

	Years ended December 31,		
	2017	2016	2015
Beginning balance	$ 2,543	$ 2,114	$ 1,772
Additions based on tax positions related to the current year	447	425	413
Additions based on tax positions related to prior years	1	18	9
Reductions for tax positions of prior years	(5)	(7)	(32)
Reductions for expiration of statute of limitations	(5)	—	—
Settlements	(28)	(7)	(48)
Ending balance	$ 2,953	$ 2,543	$ 2,114

Substantially all of the UTBs as of December 31, 2017, if recognized, would affect our effective tax rate. During the year ended December 31, 2017, we effectively settled various examinations with federal and state tax authorities for prior tax years. As a result of these developments, we remeasured our UTBs accordingly. As of December 31, 2017, we believe it is reasonably possible that our gross liabilities for UTBs may decrease by approximately $63 million within the succeeding 12 months due to the resolution of state examinations.

Interest and penalties related to UTBs are included in our provision for income taxes. During the years ended December 31, 2017, 2016 and 2015, we recognized $56 million, $125 million and $17 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. As of December 31, 2017 and 2016, accrued interest and penalties associated with UTBs were $332 million and $276 million, respectively.

The reconciliations between the federal statutory tax rate applied to income before income taxes and our effective tax rate were as follows:

	Years ended December 31,		
	2017	2016	2015
Federal statutory tax rate	35.0 %	35.0 %	35.0 %
2017 Tax Act, net repatriation tax	71.5 %	— %	— %
Foreign earnings	(15.8 %)	(15.5 %)	(18.1 %)
2017 Tax Act, net deferred tax remeasurement	(7.7 %)	— %	— %
Credits, Puerto Rico Excise Tax	(2.2 %)	(2.3 %)	(2.5 %)
Share-based payments	(0.7 %)	(1.3 %)	— %
Credits, primarily federal R&D	(0.6 %)	(0.7 %)	(1.4 %)
State taxes	0.3 %	0.1 %	0.1 %
Audit settlements (federal, state, foreign)	(0.3 %)	— %	(0.5 %)
Other, net	(0.1 %)	0.4 %	0.4 %
Effective tax rate	79.4 %	15.7 %	13.0 %

The effective tax rates for the year ended December 31, 2017, differ from the federal statutory rates due primarily to impacts of the 2017 Tax Act, including the repatriation tax on accumulated foreign earnings, offset partially by the remeasurement of certain net deferred and other tax liabilities. The effective tax rates for 2016 and 2015 differ from the federal statutory rates primarily as a result of indefinitely invested earnings of our foreign operations. In the past, we have not provided for U.S. income taxes on undistributed earnings of our foreign operations that were intended to be invested indefinitely outside the United States. Substantially all of the foreign

earnings that impact our effective tax rate results from foreign income associated with the Company's operation conducted in Puerto Rico, a territory of the United States, that is treated as a foreign jurisdiction for U.S. tax purposes, and is subject to tax incentive grants through 2035.

The U.S. territory of Puerto Rico imposes an excise tax on the gross intercompany purchase price of goods and services from our manufacturer in Puerto Rico. The rate of 4% is effective through December 31, 2027. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in cost of sales when the related products are sold. For U.S. income

tax purposes, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes when the excise tax is incurred.

Income taxes paid during the years ended December 31, 2017, 2016 and 2015, were $1.5 billion, $1.1 billion and $919 million, respectively.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely audited by the tax authorities in those jurisdictions. Significant disputes may arise with authorities involving issues of the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and the interpretation of the relevant facts. As previously disclosed, we received a Revenue Agent Report (RAR) from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. On November 29, 2017, we received a modified RAR that revised their calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution through the IRS administrative appeals process, which we believe will likely not be concluded within the next 12 months. Final resolution of the IRS audit could have a material impact on our results of operations and cash flows if not resolved favorably, however, we believe our income tax reserves are appropriately provided for all open tax years. We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009. In addition, we are currently under examination by a number of other state and foreign tax jurisdictions.

6. Earnings per share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which include primarily shares that may be issued under our stock option, restricted stock and performance unit award programs, as determined using the treasury stock method (collectively, dilutive securities).

The computation for basic and diluted EPS was as follows (in millions, except per share data):

	Years ended December 31,		
	2017	2016	2015
Income (Numerator):			
Net income for basic and diluted EPS	$ 1,979	$ 7,722	$ 6,939
Shares (Denominator):			
Weighted-average shares for basic EPS	731	748	758
Effect of dilutive securities	4	6	8
Weighted-average shares for diluted EPS	735	754	766
Basic EPS	$ 2.71	$ 10.32	$ 9.15
Diluted EPS	$ 2.69	$ 10.24	$ 9.06

For each of the three years ended December 31, 2017, the number of anti-dilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

7. Collaborations

A collaborative arrangement is a contractual arrangement that involves a joint operating activity. Such arrangements involve two or more parties that are both: (i) active participants in the activity and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for non-refundable upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments

and/or profit sharing. Our collaboration arrangements are performed with no guarantee of either technological or commercial success, and each is unique in nature. Our significant arrangements are discussed below.

Novartis AG

In April 2017, we expanded our existing migraine collaboration with Novartis AG (Novartis). In the United States, Amgen and Novartis will jointly develop and collaborate on the commercialization of Aimovig™. Amgen, as the principal, will recognize product sales of Aimovig™ in the United States, will share U.S. commercialization costs with Novartis and will pay Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig™ and other specified migraine programs. Novartis will pay Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories. Novartis will fund a portion of global R&D expenses. Novartis will also make payments to Amgen that could collectively amount to approximately $400 million if certain regulatory events occur and commercial thresholds are achieved with respect to Aimovig™ in the United States. Amgen will manufacture and supply Aimovig™ worldwide.

The migraine collaboration will continue for the commercial life of the products unless terminated in accordance with its terms.

During the years ended December 31, 2017, 2016 and 2015, costs recovered from Novartis for the migraine products were $124 million, $33 million and $6 million, respectively. Costs recovered were recorded primarily in Research and development expense in the Consolidated Statements of Income. During the year ended December 31, 2017, we received a milestone payment of $60 million from Novartis, which was recorded in Other revenues in the Consolidated Statement of Income. During the year ended December 31, 2015, we paid an upfront license fee of $30 million to Novartis, which was recorded in Research and development expense in the Consolidated Statement of Income.

Pfizer Inc.

The co-promotion term of our Enbrel® collaboration agreement with Pfizer Inc. (Pfizer) in the United States and Canada expired on October 31, 2013. Under this agreement, we paid Pfizer a profit share until October 31, 2013, and residual royalties from November 1, 2013 to October 31, 2016, which were significantly less than the profit share payments. In 2015 and 2016, the residual royalty payments ranged from 11% to 10% of annual net ENBREL sales in the United States and Canada. Effective November 1, 2016, there are no further royalty payments.

During the years ended December 31, 2016 and 2015, residual royalties due to Pfizer on ENBREL sales were $470 million and $561 million, respectively. These amounts were recorded in Selling, general and administrative expense in the Consolidated Statements of Income.

UCB

We are in a collaboration with UCB for the development and commercialization of EVENITY™. In 2016, we amended the commercialization rights and responsibilities of the parties. Under the amended agreement, we have the rights to commercialize EVENITY™ for all indications in the United States, Japan and Hong Kong. UCB has the rights for Europe, China and Brazil. The rest of the countries have been allocated to Amgen. Generally, development costs and future worldwide commercialization profits and losses related to the collaboration after accounting for expenses are shared equally. The collaboration agreement will continue in effect unless terminated earlier in accordance with its terms. During the years ended December 31, 2017, 2016 and 2015, the net costs recovered from UCB were $56 million, $48 million and $60 million, respectively, which were recorded primarily in Research and development expense in the Consolidated Statements of Income.

Bayer HealthCare Pharmaceuticals Inc.

We are in a collaboration with Bayer HealthCare Pharmaceuticals Inc. (Bayer) to jointly develop and commercialize Nexavar® worldwide, except in Japan. The rights to develop and market Nexavar® in Japan are reserved to Bayer. Nexavar® is currently marketed and sold in more than 100 countries around the world for the treatment of unresectable liver cancer and advanced kidney cancer. In the United States, Nexavar® is also approved for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

In 2015, we amended the terms of our collaboration agreement with Bayer, which terminated the co-promotion agreement in the United States, and transferred all U.S. operational responsibilities to Bayer, including commercial and medical affairs activities. Prior to the termination of the co-promotion agreement, we co-promoted Nexavar® with Bayer and shared equally in the profits or losses in the United States. In lieu of this profit share, Bayer now pays Amgen a royalty on U.S. sales of Nexavar® at a percentage rate in the high 30s. Amgen no longer contributes sales

force personnel or medical liaisons to support Nexavar® in the United States. There are no changes to the global R&D or non-U.S. profit share arrangements in the original agreement, as discussed below.

In all countries outside the United States, excluding Japan, Bayer manages all commercialization activities and incurs all of the sales and marketing expenditures and mutually agreed R&D expenses, for which we continue to reimburse Bayer for half. In these countries, we continue to receive 50% of net profits on sales of Nexavar® after deducting certain Bayer-related costs.

The agreement with Bayer will terminate at the later of the date when patents expire that were issued in connection with product candidates discovered under the agreement, or on the last day when we or Bayer market or sell products commercialized under the agreement anywhere in the world.

During the years ended December 31, 2017, 2016 and 2015, Amgen recorded Nexavar® net profits of $161 million, $167 million and $257 million, respectively, which were recognized as Other revenues in the Consolidated Statements of Income. During the years ended December 31, 2017, 2016 and 2015, Amgen recorded royalty income of $133 million, $137 million and $72 million, respectively, in Other revenues in the Consolidated Statements of Income, pursuant to the 2015 amendment to the collaboration agreement. Net R&D expenses related to the agreement were not material for the years ended December 31, 2017, 2016, and 2015.

Other

In addition to the collaborations discussed above, we have various others that are not individually significant to our business at this time. Pursuant to the terms of those agreements, we may be required to pay or we may receive additional amounts upon the achievement of various development and commercial milestones which in the aggregate could be significant. We may also incur or have reimbursed to us significant R&D costs if the related product candidate were to advance to late stage clinical trials. In addition, if any products related to these collaborations are approved for sale, we may be required to pay or we may receive significant royalties on future sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurrence.

8. Related party transactions

As of December 31, 2017 and 2016, we owned a 50% interest in K-A, a corporation formed in 1984 with Kirin Holdings Company, Limited (Kirin) for the development and commercialization of certain products based on advanced biotechnology. All of our rights to manufacture and market certain products including pegfilgrastim, granulocyte colony-stimulating factor, darbepoetin alfa, recombinant human erythropoietin and romiplostim are pursuant to exclusive licenses from K-A, which we currently market under the brand names Neulasta®, NEUPOGEN®/GRANULOKINE®, Aranesp®, EPOGEN® and Nplate®, respectively. On October 30, 2017, we announced that we agreed to acquire the remaining 50% ownership of K-A from Kirin. The transaction will be accounted for as a business combination and was completed in the first quarter of 2018, making K-A a wholly owned subsidiary of Amgen. See Note 21, Subsequent event.

Prior to the closing of the share acquisition, we accounted for our interest in K-A using the equity method and included our share of K-A's profits or losses in Selling, general and administrative expense in the Consolidated Statements of Income. For the years ended December 31, 2017, 2016 and 2015, our share of K-A's profits was $68 million, $58 million and $65 million, respectively. The carrying value of our equity method investment in K-A was $570 million and $501 million as of December 31, 2017 and 2016, respectively, and is included in Other assets in the Consolidated Balance Sheets.

K-A's revenues consist of royalty income related to its licensed technology rights. K-A receives royalty income from us, as well as from Kirin and Johnson & Johnson (J&J) under separate product license contracts for certain geographic areas outside the United States. During the years ended December 31, 2017, 2016 and 2015, K-A earned royalties from us of $221 million, $239 million and $264 million, respectively. These amounts are included in Cost of sales in the Consolidated Statements of Income.

K-A's expenses consist primarily of costs related to R&D activities conducted on its behalf by Amgen and Kirin. K-A pays Amgen and Kirin for such services at negotiated rates. During the years ended December 31, 2017, 2016 and 2015, we earned revenues from K-A of $28 million, $31 million and $65 million, respectively, for certain R&D activities performed on K-A's behalf. These amounts are recognized as Other revenues in the Consolidated Statements of Income. Cost recoveries from K-A recorded during the year ended December 31, 2017 were insignificant. During the years ended December 31, 2016 and 2015, we recorded cost recoveries from K-A of $7 million and $90 million, respectively, related to certain third-party costs. These amounts are included in Research and development expense in the Consolidated Statements of Income.

As of December 31, 2017 and 2016, we owed K-A $80 million and $69 million, respectively, which is included in Accrued liabilities in the Consolidated Balance Sheets.

Subsequent to the closing of the share acquisition, K-A's results of operations will be included in our consolidated financial statements, and as a result, transactions between us and K-A will be eliminated in consolidation. License agreements with Kirin and J&J will remain in place.

9. Available-for-sale investments

The amortized cost, gross unrealized gains, gross unrealized losses and fair values of available-for-sale investments by type of security were as follows (in millions):

	Year ended December 31, 2017			
Type of security	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
U.S. Treasury securities	$ 8,313	$ 1	$ (72)	$ 8,242
Other government-related debt securities:				
U.S.	225	—	(2)	223
Foreign and other	2,415	18	(11)	2,422
Corporate debt securities:				
Financial	10,089	17	(34)	10,072
Industrial	9,688	34	(52)	9,670
Other	1,393	3	(6)	1,390
Residential mortgage-backed securities	2,198	—	(30)	2,168
Other mortgage- and asset-backed securities	2,312	—	(15)	2,297
Money market mutual funds	3,245	—	—	3,245
Other short-term interest-bearing securities	1,440	—	—	1,440
Total interest-bearing securities	41,318	73	(222)	41,169
Equity securities	135	14	—	149
Total available-for-sale investments	$ 41,453	$ 87	$ (222)	$ 41,318

	Year ended December 31, 2016			
Type of security	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
U.S. Treasury securities	$ 6,681	$ 1	$ (68)	$ 6,614
Other government-related debt securities:				
U.S.	302	—	(3)	299
Foreign and other	1,784	9	(34)	1,759
Corporate debt securities:				
Financial	8,476	21	(37)	8,460
Industrial	8,793	59	(63)	8,789
Other	1,079	5	(7)	1,077
Residential mortgage-backed securities	1,968	1	(29)	1,940
Other mortgage- and asset-backed securities	1,731	1	(13)	1,719
Money market mutual funds	2,782	—	—	2,782
Other short-term interest-bearing securities	4,188	—	—	4,188
Total interest-bearing securities	37,784	97	(254)	37,627
Equity securities	127	31	(4)	154
Total available-for-sale investments	$ 37,911	$ 128	$ (258)	$ 37,781

The fair values of available-for-sale investments by location in the Consolidated Balance Sheets were as follows (in millions):

Consolidated Balance Sheets location	December 31, 2017	December 31, 2016
Cash and cash equivalents	$ 3,291	$ 2,783
Marketable securities	37,878	34,844
Other assets	149	154
Total available-for-sale investments	$ 41,318	$ 37,781

Cash and cash equivalents in the above table excludes bank account cash of $509 million and $458 million as of December 31, 2017 and 2016, respectively.

The fair values of available-for-sale interest-bearing security investments by contractual maturity, except for mortgage- and asset-backed securities that do not have a single maturity date, were as follows (in millions):

Contractual maturity	December 31, 2017	December 31, 2016
Maturing in one year or less	$ 6,733	$ 8,393
Maturing after one year through three years	12,820	10,404
Maturing after three years through five years	13,836	12,157
Maturing after five years through ten years	3,263	2,974
Maturing after ten years	52	40
Mortgage- and asset-backed securities	4,465	3,659
Total interest-bearing securities	$ 41,169	$ 37,627

For the years ended December 31, 2017, 2016 and 2015, realized gains were $172 million, $306 million and $132 million, respectively, and realized losses were $213 million, $367 million and $208 million, respectively. The cost of securities sold is based on the specific identification method.

Information on the fair values and gross unrealized losses of available-for-sale investments in an unrealized loss position aggregated by type and length of time that the securities have been in a continuous loss position was as follows (in millions):

	Less than 12 months		12 months or greater	
Type of security as of December 31, 2017	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	$ 7,728	$ (70)	$ 195	$ (2)
Other government-related debt securities:				
U.S.	188	(1)	34	(1)
Foreign and other	1,163	(9)	115	(2)
Corporate debt securities:				
Financial	5,928	(28)	462	(6)
Industrial	5,760	(43)	612	(9)
Other	868	(4)	117	(2)
Residential mortgage-backed securities	1,838	(24)	276	(6)
Other mortgage- and asset-backed securities	1,777	(12)	250	(3)
Total	$ 25,250	$ (191)	$ 2,061	$ (31)

Type of security as of December 31, 2016	Less than 12 months		12 months or greater	
	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	$ 5,774	$ (68)	$ —	$ —
Other government-related debt securities:				
U.S.	201	(3)	—	—
Foreign and other	1,192	(34)	17	—
Corporate debt securities:				
Financial	3,975	(37)	44	—
Industrial	3,913	(61)	149	(2)
Other	486	(7)	7	—
Residential mortgage-backed securities	1,631	(26)	158	(3)
Other mortgage- and asset-backed securities	1,087	(10)	118	(3)
Equity securities	22	(4)	—	—
Total	$ 18,281	$ (250)	$ 493	$ (8)

The primary objective of our investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

We review our available-for-sale investments for other-than-temporary declines in fair value below our cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. The evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below our cost basis and adverse conditions related specifically to the security, including any changes to the credit rating of the security, and the intent to sell, or whether we will more likely than not be required to sell, the security before recovery of its amortized cost basis. Our assessment of whether a security is other-than-temporarily impaired could change in the future based on new developments or changes in assumptions related to that particular security. As of December 31, 2017 and 2016, we believe the cost bases for our available-for-sale investments were recoverable in all material aspects.

10. Inventories

Inventories consisted of the following (in millions):

	December 31,	
	2017	2016
Raw materials	$ 232	$ 225
Work in process	1,668	1,608
Finished goods	934	912
Total inventories	$ 2,834	$ 2,745

11. Property, plant and equipment

Property, plant and equipment consisted of the following (dollar amounts in millions):

	Useful life (in years)	December 31, 2017	December 31, 2016
Land	—	$ 283	$ 295
Buildings and improvements	10-40	3,507	3,640
Manufacturing equipment	8-12	2,372	2,275
Laboratory equipment	8-12	1,179	1,092
Other	3-15	4,404	4,380
Construction in progress	—	834	745
Property, plant and equipment, gross		12,579	12,427
Less accumulated depreciation and amortization		(7,590)	(7,466)
Property, plant and equipment, net		$ 4,989	$ 4,961

During the years ended December 31, 2017, 2016 and 2015, we recognized depreciation and amortization expense associated with our property, plant and equipment of $604 million, $619 million and $727 million, respectively.

12. Goodwill and other intangible assets

Goodwill

Changes in the carrying amounts of goodwill were as follows (in millions):

	Years ended December 31, 2017	Years ended December 31, 2016
Beginning balance	$ 14,751	$ 14,787
Goodwill related to acquisitions of businesses	—	2
Currency translation adjustments	10	(38)
Ending balance	$ 14,761	$ 14,751

Other intangible assets

Other intangible assets consisted of the following (in millions):

	December 31, 2017			December 31, 2016		
	Gross carrying amount	Accumulated amortization	Other intangible assets, net	Gross carrying amount	Accumulated amortization	Other intangible assets, net
Finite-lived intangible assets:						
Developed product technology rights	$ 12,589	$ (6,796)	$ 5,793	$ 12,534	$ (5,947)	$ 6,587
Licensing rights	3,275	(1,601)	1,674	3,275	(1,300)	1,975
Marketing-related rights	1,319	(920)	399	1,333	(793)	540
R&D technology rights	1,161	(804)	357	1,122	(704)	418
Total finite-lived intangible assets	18,344	(10,121)	8,223	18,264	(8,744)	9,520
Indefinite-lived intangible assets:						
IPR&D	386	—	386	759	—	759
Total other intangible assets	$ 18,730	$ (10,121)	$ 8,609	$ 19,023	$ (8,744)	$ 10,279

Developed product technology rights consist of rights related to marketed products acquired in business combinations. Licensing rights consist primarily of contractual rights acquired in business combinations to receive future milestones, royalties and profit sharing payments, capitalized payments to third parties for milestones related to regulatory approvals to commercialize

products and up-front payments associated with royalty obligations for marketed products. Marketing-related intangible assets consist primarily of rights related to the sale and distribution of marketed products. R&D technology rights consist of technology used in R&D with alternative future uses.

IPR&D consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. During 2017, we decided to discontinue the internal development of AMG 899 acquired in the acquisition of Dezima in 2015 (see Note 3, Business combinations), resulting in an impairment charge of $400 million, which was recognized in Other operating expenses in the Consolidated Statement of Income and included in Other items, net in the Consolidated Statement of Cash Flows. See Note 16, Fair value measurement, for the impact on the related contingent consideration liabilities. As of December 31, 2017, IPR&D consists primarily of the oprozomib project, acquired in the acquisition of Onyx Pharmaceuticals, Inc. in 2013.

All IPR&D projects have major risks and uncertainties associated with the timely and successful completion of development and commercialization of product candidates, including our ability to confirm safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not permitted to market a human therapeutic without obtaining regulatory approvals, and such approvals require the completion of clinical trials that demonstrate that a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans, as well as competitive product launches, impact the revenues a product can generate. Consequently, the eventual realized value, if any, of the acquired IPR&D projects may vary from their fair values. We review IPR&D projects for impairment annually, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon the establishment of technological feasibility or regulatory approval.

During the years ended December 31, 2017, 2016 and 2015, we recognized amortization expense associated with our finite-lived intangible assets, included primarily in Cost of sales in the Consolidated Statements of Income, of $1.3 billion, $1.5 billion and $1.4 billion, respectively. The total estimated amortization expense for each of the next five years for our intangible assets is $1.2 billion, $1.1 billion, $1.1 billion, $0.9 billion and $0.9 billion in 2018, 2019, 2020, 2021 and 2022, respectively.

13. Accrued liabilities

Accrued liabilities consisted of the following (in millions):

	December 31,	
	2017	2016
Sales deductions	$ 2,247	$ 1,874
Dividends payable	953	849
Employee compensation and benefits	816	920
Sales returns reserve	455	437
Other	2,045	1,804
Total accrued liabilities	$ 6,516	$ 5,884

14. Financing arrangements

The carrying values and the fixed contractual coupon rates of our borrowings were as follows (in millions):

	December 31,	
	2017	2016
Short-term loan	$ —	$ 605
2.125% notes due 2017 (2.125% 2017 Notes)	—	1,250
Floating Rate Notes due 2017	—	600
1.25% notes due 2017 (1.25% 2017 Notes)	—	850
5.85% notes due 2017 (5.85% 2017 Notes)	—	1,100
6.15% notes due 2018 (6.15% 2018 Notes)	500	500
4.375% €550 million notes due 2018 (4.375% 2018 euro Notes)	653	577
5.70% notes due 2019 (5.70% 2019 Notes)	1,000	1,000
1.90% notes due 2019 (1.90% 2019 Notes)	700	—
Floating Rate Notes due 2019	550	250
2.20% notes due 2019 (2.20% 2019 Notes)	1,400	1,400
2.125% €675 million notes due 2019 (2.125% 2019 euro Notes)	810	710
4.50% notes due 2020 (4.50% 2020 Notes)	300	300
2.125% notes due 2020 (2.125% 2020 Notes)	750	750
Floating Rate Notes due 2020	300	—
2.20% notes due 2020 (2.20% 2020 Notes)	700	—
3.45% notes due 2020 (3.45% 2020 Notes)	900	900
4.10% notes due 2021 (4.10% 2021 Notes)	1,000	1,000
1.85% notes due 2021 (1.85% 2021 Notes)	750	750
3.875% notes due 2021 (3.875% 2021 Notes)	1,750	1,750
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	1,501	1,315
2.70% notes due 2022 (2.70% 2022 Notes)	500	500
2.65% notes due 2022 (2.65% 2022 Notes)	1,500	—
3.625% notes due 2022 (3.625% 2022 Notes)	750	750
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	719	687
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
3.125% notes due 2025 (3.125% 2025 Notes)	1,000	1,000
2.00% €750 million notes due 2026 (2.00% 2026 euro Notes)	901	789
2.60% notes due 2026 (2.60% 2026 Notes)	1,250	1,250
5.50% £475 million notes due 2026 (5.50% 2026 pound sterling Notes)	642	586
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	—
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	946	864
6.375% notes due 2037 (6.375% 2037 Notes)	552	552
6.90% notes due 2038 (6.90% 2038 Notes)	291	291
6.40% notes due 2039 (6.40% 2039 Notes)	466	466
5.75% notes due 2040 (5.75% 2040 Notes)	412	412
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	974	974
5.65% notes due 2042 (5.65% 2042 Notes)	487	487
5.375% notes due 2043 (5.375% 2043 Notes)	261	261
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415

4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(929)	(936)
Total carrying value of debt	35,342	34,596
Less current portion	(1,152)	(4,403)
Total noncurrent debt	$ 34,190	$ 30,193

There are no material differences between the effective interest rates and coupon rates of any of our borrowings, except for the 4.563% 2048 Notes and the 4.663% 2051 Notes, which have effective interest rates of 6.3% and 5.6%, respectively.

Under the terms of all of our outstanding notes (including debt exchange issuances discussed below), except our Other notes due 2097, in the event of a change-in-control triggering event, we may be required to purchase all or a portion of these debt securities at a price equal to 101% of the principal amount of the notes plus accrued and unpaid interest. In addition, all of our outstanding notes, except for our floating-rate notes, 0.41% 2023 Swiss franc Bonds and Other notes due 2097, may be redeemed at any time at our option, in whole or in part, at the principal amount of the notes being redeemed plus accrued and unpaid interest and a make-whole amount, which is defined by the terms of the notes. Certain of the redeemable notes do not require the payment of a make-whole amount if redeemed during a specified period of time immediately prior to the maturity of the notes. Such time periods range from one to six months prior to maturity.

Debt issuances

We issued debt and debt securities in various offerings during the years ended December 31, 2017, 2016 and 2015 including:

- In 2017, we issued $4.5 billion principal amount of notes, consisting of the Floating-Rate Notes due 2019, the 1.90% 2019 Notes, the Floating-Rate Notes due 2020, the 2.20% 2020 Notes, the 2.65% 2022 Notes and the 3.20% 2027 Notes.

- In 2016, we issued $6.7 billion principal amount of notes, consisting of the 1.85% 2021 Notes, 1.25% 2022 euro Notes, 0.41% 2023 Swiss franc Bonds, 2.25% 2023 Notes, 2.00% 2026 euro Notes, 2.60% 2026 Notes and $1.0 billion of the 4.40% 2045 Notes. We received a $79 million premium on the 4.40% 2045 Notes. In addition, we borrowed $605 million under a short-term floating rate loan.

- In 2015, we issued $3.5 billion aggregate principal amount of notes, consisting of the 2.125% 2020 Notes, the 2.70% 2022 Notes, the 3.125% 2025 Notes and $1.25 billion of the 4.40% 2045 Notes.

As of December 31, 2017, we have a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working capital needs. During the year ended December 31, 2017, we issued and repaid an aggregate of $12.3 billion commercial paper and had a maximum outstanding balance of $1.5 billion under our commercial paper program. During the years ended December 31, 2016 and 2015, we did not issue any commercial paper. No commercial paper was outstanding as of December 31, 2017 or 2016.

Debt repayments

In 2017, we repaid the $605 million short-term floating rate loan, the $1.25 billion aggregate principal amount of the 2.125% 2017 Notes, the $600 million aggregate principal amount of the Floating-Rate Notes due 2017, the $850 million aggregate principal amount of the 1.25% 2017 Notes and the $1.1 billion aggregate principal amount of the 5.85% 2017 Notes. In 2016, we repaid $3.7 billion of debt, including the remaining $1.975 billion of principal on a term loan credit facility, the $750 million aggregate principal amount of the 2.30% 2016 Notes and the $1.0 billion aggregate principal amount of the 2.50% 2016 Notes. In 2015, we repaid $2.4 billion of principal on a term loan credit facility.

Debt exchange

During 2016, we completed a private offering to exchange portions of certain outstanding senior notes due 2037 through 2043 (collectively, the Old Notes), listed below, for new senior notes, consisting of principal amounts of $1.4 billion of 4.563% 2048 Notes and $3.5 billion of 4.663% 2051 Notes (collectively, the New Notes).

The following principal amounts of each series of Old Notes were validly tendered and subsequently canceled (in millions):

	Principal amount exchanged
6.375% 2037 Notes	$ 348
6.90% 2038 Notes	209
6.40% 2039 Notes	534
5.75% 2040 Notes	288

5.15% 2041 Notes	1,276
5.65% 2042 Notes	763
5.375% 2043 Notes	739

The New Notes bear lower fixed-coupon rates while requiring higher principal repayments on extended maturity dates, compared with the Old Notes that were exchanged. There were no other significant changes to the terms between the Old Notes and the New Notes. The exchange was accounted for as a debt modification, and there were no cash payments to or cash receipts from the note holders as a result of the exchange. Existing deferred financing costs associated with the Old Notes, as well as

discounts associated with the New Notes aggregating $801 million, are being accreted over the term of the New Notes and recorded as Interest expense, net, in the Consolidated Statements of Income. Transaction costs of $24 million incurred for the exchange were expensed immediately in Interest and other income, net, in the Consolidated Statement of Income.

Interest rate swaps

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted fixed-rate interest coupons for certain of our debt issuances to floating London Interbank Offered Rate (LIBOR)-based coupons over the lives of the respective notes. These interest rate swap contracts qualified and are designated as fair value hedges. The effective interest rates on notes for which we have entered into interest rate swap contracts and the related notional amounts of these contracts were as follows (dollar amounts in millions):

		December 31,	
		2017	2016
Notes	Effective interest rate	Notional amount	
1.25% 2017 Notes	LIBOR + 0.4%	$ —	$ 850
2.20% 2019 Notes	LIBOR + 0.6%	1,400	1,400
3.45% 2020 Notes	LIBOR + 1.1%	900	900
4.10% 2021 Notes	LIBOR + 1.7%	1,000	1,000
3.875% 2021 Notes	LIBOR + 2.0%	1,750	1,750
3.625% 2022 Notes	LIBOR + 1.6%	750	750
3.625% 2024 Notes	LIBOR + 1.4%	1,400	—
3.125% 2025 Notes	LIBOR + 0.9%	1,000	—
2.600% 2026 Notes	LIBOR + 0.3%	1,250	—
Total notional amounts		$ 9,450	$ 6,650

Cross-currency swaps

In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. The terms of these contracts effectively convert the interest payments and principal repayment on our 2.125% 2019 euro Notes, 1.25% 2022 euro Notes, 0.41% 2023 Swiss franc Bonds, 2.00% 2026 euro Notes, 5.50% 2026 pound sterling Notes and 4.00% 2029 pound sterling Notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts have been designated as cash flow hedges. For information regarding the terms of these contracts, see Note 17, Derivative instruments.

Shelf registration statements and other facilities

In 2014, we entered into a $2.5 billion syndicated, unsecured, revolving credit agreement which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $500 million with the agreement of the banks. Each bank which is a party to the agreement has an initial commitment term of five years. We extended this term by one year during 2016 and may extend the term for an additional year with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest at LIBOR plus 1% for any amounts borrowed under this facility. As of December 31, 2017 and 2016, no amounts were outstanding under this facility.

In 2017, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2020.

Certain of our financing arrangements contain non-financial covenants. In addition, our revolving credit agreement includes a financial covenant with respect to the level of our borrowings in relation to our equity, as defined. We were in compliance with all applicable covenants under these arrangements as of December 31, 2017.

Contractual maturities of debt obligations

The aggregate contractual maturities of all borrowings due subsequent to December 31, 2017, are as follows (in millions):

Maturity date	Amount
2018	$ 1,153
2019	4,460
2020	2,950
2021	3,500
2022	4,251
Thereafter	19,957
Total	$ 36,271

Interest costs

Interest costs are expensed as incurred, except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest expense, net, for the years ended December 31, 2017, 2016 and 2015, was $1.3 billion, $1.3 billion and $1.1 billion, respectively. Interest costs capitalized for the years ended December 31, 2017, 2016 and 2015, were not material. Interest paid, including the ongoing impact and settlements of interest rate and cross-currency swap contracts, during the years ended December 31, 2017, 2016 and 2015, was $1.3 billion, $1.2 billion and $1.0 billion, respectively.

15. Stockholders' equity

Stock repurchase program

Activity under our stock repurchase program, on a trade date basis, was as follows (in millions):

	Years ended December 31,					
	2017		2016		2015	
	Shares	Dollars	Shares	Dollars	Shares	Dollars
First quarter	3.4	$ 555	4.7	$ 690	2.9	$ 451
Second quarter	6.2	1,006	3.9	591	3.3	515
Third quarter	4.4	769	4.4	747	4.6	703
Fourth quarter	4.5	796	6.7	999	1.2	184
Total stock repurchases	18.5	$ 3,126	19.7	$ 3,027	12.0	$ 1,853

As of December 31, 2017, $4.4 billion remained available under our stock repurchase program. In January 2018, our Board of Directors authorized an additional $10.0 billion under our stock repurchase program. On February 5, 2018, we announced a tender offer to purchase up to $10.0 billion of our common stock at a price not greater than $200 per share nor less than $175 per share. The tender offer expires at 12:00 Midnight, New York City time, at the end of Monday, March 5, 2018, unless the offer is extended.

Dividends

Our Board of Directors declared quarterly dividends per share of $1.15, $1.00 and $0.79 that were paid in each of the four quarters of 2017, 2016, and 2015, respectively.

Historically, each year we have declared dividends in December that were paid in the first quarter of the following fiscal year, and in March, July and October that were paid in the second, third and fourth quarters, respectively, of the same fiscal year.

Additionally, on December 12, 2017, the Board of Directors declared a quarterly cash dividend of $1.32 per share of common stock, which will be paid on March 8, 2018, to all stockholders of record as of the close of business on February 15, 2018.

Accumulated other comprehensive income (loss)

The components of AOCI were as follows (in millions):

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2014	$ (264)	$ 290	$ (19)	$ (15)	$ (8)
Foreign currency translation adjustments	(257)	—	—	—	(257)
Unrealized gains (losses)	—	150	(299)	8	(141)
Reclassification adjustments to income	—	(143)	76	—	(67)
Other	—	—	—	1	1
Income taxes	10	—	(18)	—	(8)
Balance as of December 31, 2015	(511)	297	(260)	(6)	(480)
Foreign currency translation adjustments	(93)	—	—	—	(93)
Unrealized (losses) gains	—	(176)	63	—	(113)
Reclassification adjustments to income	—	139	61	—	200
Other	—	—	—	1	1
Income taxes	(6)	22	(2)	—	14
Balance as of December 31, 2016	(610)	282	(138)	(5)	(471)
Foreign currency translation adjustments	77	—	—	—	77
Unrealized gains (losses)	—	192	(46)	—	146
Reclassification adjustments to income	—	(638)	41	—	(597)
Other	—	—	—	5	5
Income taxes	4	158	(1)	—	161
Balance as of December 31, 2017	$ (529)	$ (6)	$ (144)	$ —	$ (679)

With respect to the table above, income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for cash flow hedges were a $68 million expense and $226 million benefit in 2017, a $68 million benefit and $46 million expense in 2016 and a $53 million expense and $53 million benefit in 2015, respectively. Income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for available-for-sale securities were a $9 million expense and $8 million benefit for 2017, a $9 million benefit and $11 million expense in 2016 and a $0 million benefit and $18 million expense in 2015, respectively.

The reclassifications out of AOCI to earnings were as follows (in millions):

	Years ended December 31,			
Components of AOCI	2017	2016	2015	Consolidated Statements of Income location
Cash flow hedges:				
Foreign currency contract gains	$ 65	$ 308	$ 326	Product sales
Cross-currency swap contract gains (losses)	574	(446)	(182)	Interest and other income, net
Forward interest rate contract losses	(1)	(1)	(1)	Interest expense, net
	638	(139)	143	Income before income taxes
	(226)	46	(53)	Provision for income taxes
	$ 412	$ (93)	$ 90	Net income

Available-for-sale securities:				
Net realized losses	$ (41)	$ (61)	$ (76)	Interest and other income, net
	(8)	11	18	Provision for income taxes
	$ (49)	$ (50)	$ (58)	Net income

Other

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. As of December 31, 2017 and 2016, no shares of preferred stock were issued or outstanding.

16. Fair value measurement

To estimate the fair value of our financial assets and liabilities, we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing an asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing an asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access

Level 2 — Valuations for which all significant inputs are observable, either directly or indirectly, other than level 1 inputs

Level 3 — Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

The fair values of each major class of the Company's financial assets and liabilities measured at fair value on a recurring basis were as follows (in millions):

Fair value measurement as of December 31, 2017, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale investments:				
U.S. Treasury securities	$ 8,242	$ —	$ —	$ 8,242
Other government-related debt securities:				
U.S.	—	223	—	223
Foreign and other	—	2,422	—	2,422
Corporate debt securities:				
Financial	—	10,072	—	10,072
Industrial	—	9,670	—	9,670
Other	—	1,390	—	1,390
Residential mortgage-backed securities	—	2,168	—	2,168
Other mortgage- and asset-backed securities	—	2,297	—	2,297
Money market mutual funds	3,245	—	—	3,245
Other short-term interest-bearing securities	—	1,440	—	1,440
Equity securities	149	—	—	149
Derivatives:				
Foreign currency contracts	—	6	—	6
Cross-currency swap contracts	—	270	—	270
Interest rate swap contracts	—	10	—	10
Total assets	$ 11,636	$ 29,968	$ —	$ 41,604
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 204	$ —	$ 204
Cross-currency swap contracts	—	220	—	220
Interest rate swap contracts	—	61	—	61
Contingent consideration obligations in connection with business combinations	—	—	69	69
Total liabilities	$ —	$ 485	$ 69	$ 554

Fair value measurement as of December 31, 2016, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale investments:				
U.S. Treasury securities	$ 6,614	$ —	$ —	$ 6,614
Other government-related debt securities:				
U.S.	—	299	—	299
Foreign and other	—	1,759	—	1,759
Corporate debt securities:				
Financial	—	8,460	—	8,460
Industrial	—	8,789	—	8,789
Other	—	1,077	—	1,077
Residential mortgage-backed securities	—	1,940	—	1,940
Other mortgage- and asset-backed securities	—	1,719	—	1,719
Money market mutual funds	2,782	—	—	2,782
Other short-term interest-bearing securities	—	4,188	—	4,188
Equity securities	154	—	—	154
Derivatives:				
Foreign currency contracts	—	203	—	203
Interest rate swap contracts	—	41	—	41
Total assets	$ 9,550	$ 28,475	$ —	$ 38,025
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 4	$ —	$ 4
Cross-currency swap contracts	—	523	—	523
Interest rate swap contracts	—	7	—	7
Contingent consideration obligations in connection with business combinations	—	—	179	179
Total liabilities	$ —	$ 534	$ 179	$ 713

Excluded from the tables above are limited partnership investments of $213 million and $158 million as of December 31, 2017 and 2016, respectively, which are included in Other assets in the Consolidated Balance Sheets. These investments are measured using net asset values of the underlying investments as a practical expedient. These investments are typically only redeemable through distributions upon liquidation of the underlying assets. As of December 31, 2017, unfunded additional commitments to be made over the next several years for these investments were approximately $100 million.

The fair values of our U.S. Treasury securities, money market mutual funds and equity securities are based on quoted market prices in active markets with no valuation adjustment.

Most of our other government-related and corporate debt securities are investment grade and have maturity dates of five years or less from the balance sheet date. Our other government-related debt securities portfolio is composed of securities with weighted-average credit ratings of BBB+ or equivalent by Standard & Poor's Financial Services LLC (S&P), and A- or equivalent by Moody's Investors Service, Inc. (Moody's) or Fitch Ratings Inc. (Fitch); and our corporate debt securities portfolio has a weighted-average credit rating of A- or equivalent by Fitch, and BBB+ or equivalent by S&P or Moody's. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are

observable, either directly or indirectly, to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

Our residential mortgage-, other mortgage- and asset-backed securities portfolio is composed entirely of senior tranches, with credit ratings of AAA by S&P, Moody's or Fitch. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. The inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

We value our other short-term interest-bearing securities at amortized cost, which approximates fair value given their near-term maturity dates.

All of our foreign currency forward and option derivatives contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A- or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable, either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. These inputs, where applicable, are at commonly quoted intervals. See Note 17, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A- or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. See Note 17, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A- or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by using an income-based industry standard valuation model for which all significant inputs were observable either directly or indirectly. These inputs include LIBOR, swap rates and obligor credit default swap rates.

Contingent consideration obligations

As a result of our business acquisitions, we incurred contingent consideration obligations, as discussed below. The contingent consideration obligations are recorded at their fair values by using probability-adjusted discounted cash flows, and we revalue these obligations each reporting period until the related contingencies have been resolved. The fair value measurements of these obligations are based on significant unobservable inputs related to product candidates acquired in business combinations and are reviewed quarterly by management in our R&D and commercial sales organizations. These inputs include, as applicable, estimated probabilities and timing of achieving specified regulatory and commercial milestones and estimated annual sales. Significant changes that increase or decrease the probabilities of achieving the related regulatory and commercial events, that shorten or lengthen the time required to achieve such events, or that increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of the obligations, as applicable. Changes in the fair values of contingent consideration obligations are recognized in Other operating expenses in the Consolidated Statements of Income.

Changes in the carrying amounts of contingent consideration obligations were as follows (in millions):

	Years ended December 31,		
	2017	2016	2015
Beginning balance	$ 179	$ 188	$ 215
Addition from Dezima acquisition	—	—	110
Payment to former BioVex Group, Inc. shareholders	—	—	(125)
Net changes in valuation	(110)	(9)	(12)
Ending balance	$ 69	$ 179	$ 188

As a result of our acquisition of Dezima in 2015, we are obligated to pay its former shareholders up to $1.25 billion of additional consideration contingent upon achieving certain development and sales-related milestones and

low single-digit royalties on net product sales above a certain threshold for AMG 899. The fair values of the contingent consideration obligations had an aggregate value of $110 million at acquisition. During 2017, we decided to discontinue the internal development of AMG 899, and accordingly, reduced to zero these contingent consideration liabilities. The remeasurement of these liabilities was included in

Other items, net in the Consolidated Statement of Cash Flows during the year ended December 31, 2017. See Note 12, Goodwill and other intangible assets, for the impact on the related IPR&D asset.

As a result of our acquisition of BioVex Group Inc. in 2011, we are obligated to pay its former shareholders additional consideration contingent upon achieving separate regulatory and sales-related milestones with regard to IMLYGIC®, including a $125 million milestone payment made in 2015 as a result of the first commercial sale of this product in the United States following marketing approval. The remaining milestone payments of up to $325 million will become payable if certain sales thresholds related to IMLYGIC® are achieved within specified periods of time.

During the years ended December 31, 2017 and 2016, there were no transfers of assets or liabilities between fair value measurement levels, and, except with respect to an IPR&D asset discussed in Note 12, Goodwill and other intangible assets, there were no material remeasurements to the fair values of assets and liabilities that are not measured at fair value on a recurring basis.

Summary of the fair values of other financial instruments

Cash equivalents

The fair values of cash equivalents approximate their carrying values due to the short-term nature of such financial instruments.

Borrowings

We estimated the fair value of our borrowings (Level 2) by taking into consideration indicative prices obtained from a third-party financial institution that utilizes industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly. These inputs include reported trades of and broker-dealer quotes on the same or similar securities; credit spreads; benchmark yields; foreign currency exchange rates, as applicable; and other observable inputs. As of December 31, 2017 and 2016, the aggregate fair values of our borrowings were $38.6 billion and $36.5 billion, respectively, and the carrying values were $35.3 billion and $34.6 billion, respectively.

17. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we utilize or have utilized certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We do not use derivatives for speculative trading purposes.

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, associated primarily with our euro-denominated international product sales. Increases and decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are offset partially by corresponding increases and decreases in the cash flows from our international operating expenses resulting from these foreign currency exchange rate movements. To further reduce our exposure to foreign currency exchange rate fluctuations on our international product sales, we enter into foreign currency forward and option contracts to hedge a portion of our projected international product sales primarily over a three-year time horizon, with, at any given point in time, a higher percentage of nearer-term projected product sales being hedged than in successive periods.

As of December 31, 2017, 2016 and 2015, we had open foreign currency forward contracts with notional amounts of $4.6 billion, $3.4 billion and $3.3 billion, respectively, and open foreign currency option contracts with notional amounts of $74 million, $608 million and $225 million, respectively. We have designated these foreign currency forward and foreign currency option contracts, which are primarily euro based, as cash flow hedges; and accordingly, we report the effective portions of the unrealized gains and losses on these contracts in AOCI in the Consolidated Balance Sheets, and we reclassify them to earnings in the same periods during which the hedged transactions affect earnings.

To manage counterparty risk resulting from favorable movements in U.S. dollar/foreign currency exchange rates, we effectively terminated outstanding foreign currency forward and option contracts with a notional amount of $2.3 billion during the year ended December 31, 2015. We received $340 million from the counterparties, which was included in Net cash provided by operating activities in the Consolidated Statement of Cash Flows. This amount was recorded in AOCI and is being recognized in Product sales in the Consolidated Statements of Income when the

related international product sales affect earnings. In addition, during the year ended December 31, 2015, we entered into new foreign currency forward and option contracts that hedge these forecasted international product sales.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term debt denominated in foreign currencies, we enter into cross-currency swap contracts. Under the terms of such contracts, we paid euros, pounds sterling and Swiss francs and received U.S. dollars for the notional amounts at the inception of the contracts; and based on these notional amounts, we exchange interest payments at fixed rates over the lives of the contracts by paying U.S. dollars and receiving euros, pounds sterling and Swiss francs. In addition, we will pay U.S. dollars to and receive euros, pounds sterling and Swiss francs from the counterparties at the maturities of the contracts for these same notional amounts. The terms of these contracts correspond to the related hedged debt, effectively converting the interest payments and principal repayment on the debt from euros, pounds sterling and Swiss francs to U.S. dollars. We have designated these cross-currency swap contracts as cash flow hedges, and accordingly, the effective portions of the unrealized gains and losses on these contracts are reported in AOCI in the Consolidated Balance Sheets and reclassified to earnings in the same periods during which the hedged debt affects earnings.

The notional amounts and interest rates of our cross-currency swaps as of December 31, 2017, were as follows (notional amounts in millions):

	Foreign currency			U.S. dollars		
Hedged notes		**Notional amount**	**Interest rate**		**Notional amount**	**Interest rate**
2.125% 2019 euro Notes	€	675	2.125 %	$	864	2.6 %
1.25% 2022 euro Notes	€	1,250	1.25 %	$	1,388	3.2 %
0.41 % 2023 Swiss franc Bonds	CHF	700	0.41 %	$	704	3.4 %
2.00% 2026 euro Notes	€	750	2.00 %	$	833	3.9 %
5.50% 2026 pound sterling Notes	£	475	5.50 %	$	747	6.0 %
4.00% 2029 pound sterling Notes	£	700	4.00 %	$	1,111	4.5 %

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Consolidated Balance Sheets and are amortized into earnings over the lives of the associated debt issuances.

The effective portions of unrealized gains and losses recognized in AOCI for our derivative instruments designated as cash flow hedges were as follows (in millions):

	Years ended December 31,		
Derivatives in cash flow hedging relationships	**2017**	**2016**	**2015**
Foreign currency contracts	$ (402)	$ 115	$ 425
Cross-currency swap contracts	581	(281)	(275)
Forward interest rate contracts	13	(10)	—
Total unrealized gains (losses)	$ 192	$ (176)	$ 150

The locations in the Consolidated Statements of Income and the effective portions of the gains and losses reclassified out of AOCI and into earnings for our derivative instruments designated as cash flow hedges were as follows (in millions):

		Years ended December 31,		
Derivatives in cash flow hedging relationships	**Consolidated Statements of Income location**	**2017**	**2016**	**2015**
Foreign currency contracts	Product sales	$ 65	$ 308	$ 326
Cross-currency swap contracts	Interest and other income, net	574	(446)	(182)
Forward interest rate contracts	Interest expense, net	(1)	(1)	(1)

Total realized gains (losses)	$ 638	$ (139)	$ 143

No portions of our cash flow hedge contracts are excluded from the assessment of hedge effectiveness, and the gains and losses of the ineffective portions of these hedging instruments were not material for the years ended December 31, 2017, 2016

and 2015. As of December 31, 2017, the amounts expected to be reclassified out of AOCI and into earnings over the next 12 months are $175 million of net losses on our foreign currency and cross-currency swap contracts. The net amount expected to be reclassified out of AOCI and into earnings over the next 12 months on our forward interest rate contracts is not material.

Fair value hedges

To achieve the desired mix of fixed and floating interest rates on our long-term debt, we entered into interest rate swap contracts that qualified and are designated as fair value hedges. The terms of these interest rate swap contracts correspond to the related hedged debt instruments and effectively convert a fixed interest rate coupon to a floating LIBOR-based coupon over the lives of the respective notes. As of December 31, 2017 and 2016, we had interest rate swap agreements with aggregate notional amounts of $9.45 billion and $6.65 billion, respectively, that hedge certain of our long-term debt issuances. See Note 14, Financing arrangements—Interest rate swaps.

For derivative instruments that qualify for and are designated as fair value hedges, we recognize in earnings the unrealized gain or loss on the derivative resulting from the change in fair value during the period as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. During the years ended December 31, 2017 and 2016, we included unrealized losses on interest rate swap agreements of $85 million and $34 million, respectively, in the same line item, Interest expense, net, in the Consolidated Statements of Income, as the offsetting unrealized gains of $85 million and $34 million, respectively, on the related hedged debt. During the year ended December 31, 2015, we included unrealized gains on interest rate swap agreements of $48 million in the same line item, Interest expense, net, in the Consolidated Statement of Income, as the offsetting unrealized losses of $48 million on the related hedged debt.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. These exposures are hedged on a month-to-month basis. As of December 31, 2017, 2016 and 2015, the total notional amounts of these foreign currency forward contracts were $757 million, $666 million and $911 million, respectively.

The location in the Consolidated Statements of Income and the amount of gains (losses) recognized in earnings for our derivative instruments not designated as hedging instruments were as follows (in millions):

		Years ended December 31,		
Derivatives not designated as hedging instruments	**Consolidated Statements of Income location**	**2017**	**2016**	**2015**
Foreign currency contracts	Interest and other income, net	$ 24	$ (56)	$ (16)

The fair values of derivatives included on the Consolidated Balance Sheets were as follows (in millions):

	Derivative assets		Derivative liabilities	
December 31, 2017	Consolidated Balance Sheet location	Fair value	Consolidated Balance Sheet location	Fair value
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other noncurrent assets	$ 6	Accrued liabilities/ Other noncurrent liabilities	$ 204
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	270	Accrued liabilities/ Other noncurrent liabilities	220
Interest rate swap contracts	Other current assets/ Other noncurrent assets	10	Accrued liabilities/ Other noncurrent liabilities	61
Total derivatives designated as hedging instruments		$ 286		$ 485

	Derivative assets		Derivative liabilities	
December 31, 2016	Consolidated Balance Sheet location	Fair value	Consolidated Balance Sheet location	Fair value
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other noncurrent assets	$ 203	Accrued liabilities/ Other noncurrent liabilities	$ 4
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	523
Interest rate swap contracts	Other current assets/ Other noncurrent assets	41	Accrued liabilities/ Other noncurrent liabilities	7
Total derivatives designated as hedging instruments		$ 244		$ 534

Our derivative contracts that were in liability positions as of December 31, 2017, contain certain credit-risk-related contingent provisions that would be triggered if: (i) we were to undergo a change in control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the contracts may only be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

The cash flow effects of our derivative contracts are included within Net cash provided by operating activities in the Consolidated Statements of Cash Flows.

18. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See Part I, Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations*. We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote.

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Our legal proceedings involve various aspects of our business and a variety of claims-including but not limited to patent validity and infringement, regulatory standards, marketing, and other corporate and commercial matters-some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing, plaintiffs seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process, which in complex proceedings of the sort we face often extend for several years. As a result, none of the matters pending against us described in this filing have progressed sufficiently through discovery and/or the development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain of our legal proceedings and other matters are discussed below:

PCSK9 Antibody Patent Litigation

U.S. Patent Litigation—Sanofi/Regeneron

On October 17, 2014, Amgen initiated a series of lawsuits in the U.S. District Court for the District of Delaware (the Delaware District Court) against Sanofi, Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc., and Regeneron Pharmaceuticals, Inc. (Regeneron) for patent infringement. On December 15, 2014, these lawsuits were consolidated by the Delaware District Court into a single case against Sanofi, Sanofi-Aventis U.S. LLC and Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc. (collectively, Sanofi) and Regeneron, addressing seven of our patents: U.S. Patent Nos. 8,563,698; 8,829,165 (the ’165 Patent); 8,859,741 (the ’741 Patent); 8,871,913; 8,871,914; 8,883,983; and 8,889,834. These patents describe and claim monoclonal antibodies to proprotein convertase subtilisin/kexin type 9 (PCSK9). By its complaints, Amgen seeks an injunction to prevent the infringing manufacture, use and sale of Sanofi and Regeneron’s alirocumab, a monoclonal antibody targeting PCSK9. On January 29, 2016, the Delaware District Court granted Amgen’s motion to amend the complaint to add Amgen Manufacturing, Limited (AML) and Amgen USA Inc. as plaintiffs and to add the allegation that defendants’ infringement of Amgen’s patents is willful.

On February 22, 2016, the Delaware District Court entered a stipulated order finding alirocumab and the drug product containing it, PRALUENT®, infringe certain of Amgen’s patents, including claims 2, 7, 9, 15, 19 and 29 of the ’165 Patent and claim 7 of the ’741 Patent. On March 18, 2016, the Delaware District Court entered judgment in favor of Amgen following a five-day jury trial and a unanimous jury verdict that these patent claims from the ’165 Patent and the ’741 Patent are all valid. On January 3, 2017, the Delaware District Court denied Sanofi and Regeneron’s post-trial motions seeking a new trial and for judgment as a matter of law, and on January 5, 2017, granted Amgen’s motion for a permanent injunction prohibiting the infringing manufacture, use, sale, offer for sale or import of alirocumab in the United States.

On January 12, 2017, Sanofi and Regeneron filed an appeal of the judgment and the permanent injunction to the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court). Following a motion by Sanofi and Regeneron, the Federal Circuit Court ordered an expedited briefing schedule for the appeal and, on February 8, 2017, entered a stay of the permanent injunction during the pendency of the appeal. On October 5, 2017, the Federal Circuit Court reversed-in-part the judgment of the Delaware District Court and remanded for a new trial two of defendants’ patent validity defenses (failure to meet the law’s requirements for patentability of written description and enablement of the claimed inventions), and affirmed the Delaware District Court’s judgment of infringement of claims 2, 7, 9, 15, 19 and 29 of the ’165 Patent and claim 7 of the ’741 Patent and patent validity on the defendants’ third patent validity defense (finding that the claimed inventions were not obvious to a person of ordinary skill in the field of the patents). The Federal Circuit Court also vacated and remanded for further consideration by the Delaware District Court the permanent injunction. On December 6, 2017, Amgen petitioned the Federal Circuit Court for rehearing *en banc*.

Patent Disputes in the European Region

On February 24, 2016, the European Patent Office (EPO) granted European Patent No. 2,215,124 (EP 2,215,124) to Amgen. This patent describes and claims monoclonal antibodies to PCSK9 and methods of treatment. On February 24, 2016, Sanofi filed an opposition to the patent in the EPO seeking to invalidate it. In November

2016, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A. and Sanofi Winthrop Industrie S.A. filed a joint opposition against Amgen's patent, and each of Eli Lilly and Company, Regeneron, and Strawman Ltd. also filed oppositions to Amgen's patent. Amgen filed its response on May 2, 2017. The EPO has scheduled oral proceedings to begin on November 28, 2018.

We are also involved in and expect future involvement in additional disputes regarding our PCSK9 patents in other jurisdictions and regions, including matters filed against us and that we have filed in the United Kingdom, Germany and France.

Sensipar® (cinacalcet) Litigation

Sensipar® Abbreviated New Drug Application (ANDA) Patent Litigation

Beginning in September 2016, Amgen filed 14 separate lawsuits in the Delaware District Court for infringement of our U.S. Patent No. 9,375,405 (the '405 Patent) against: (1) Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc., (2) Micro Labs Ltd. and Micro Labs USA, Inc. (collectively, Micro Labs), (3) Watson Laboratories, Inc., Actavis, Inc. and Actavis Pharma, Inc., (4) Cipla Limited and Cipla USA, Inc. (collectively, Cipla), (5) Strides Pharma Global PTE Limited and Strides Pharma, Inc., (6) Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. (collectively, Sun), (7) Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, Dr. Reddy's), (8) Ajanta Pharma Limited and Ajanta Pharma USA, Inc. (collectively, Ajanta), (9) Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, and Amneal Pharmaceuticals Co. India Private Limited, (10) Apotex Inc. and Apotex Corp. (collectively, Apotex), (11) Hetero USA Inc., Hetero Labs Ltd. and Hetero Labs Ltd. Unit V (collectively, Hetero), (12) Breckenridge Pharmaceutical, Inc. (Breckenridge), (13) Mylan Pharmaceuticals Inc. and Mylan Inc., and (14) Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, Zydus). In November 2016, Actavis, Inc. was dismissed from the applicable lawsuit by joint stipulation of the parties. The Delaware District Court consolidated these 14 lawsuits into a single case, *Amgen Inc. v. Aurobindo Pharma Ltd. et al.*, which is scheduled for trial on March 5, 2018. The '405 Patent is entitled "Rapid Dissolution Formulation of a Calcium Receptor-Active Compound" and expires in 2026. Amgen seeks an order of the Delaware District Court making any U.S. Food and Drug Administration (FDA) approval of the defendants' generic versions of Sensipar® effective no earlier than the expiration of the '405 Patent. All defendants have responded to the complaint denying infringement and seeking judgment that the '405 Patent is invalid and/or not infringed. Amgen filed, and the Delaware District Court signed, stipulated dismissals of the lawsuit against defendants Apotex on September 11, 2017, and Micro Labs on September 20, 2017. The Delaware District Court signed consent judgments filed by Amgen and Breckenridge on September 21, 2017, by Amgen and Sun on November 2, 2017, by Amgen and Hetero on November 2, 2017, and by Amgen and Ajanta on November 9, 2017, each stipulating to entry of judgment of infringement and validity of the '405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of, or distribution into the United States of the respective defendant's cinacalcet product during the term of the '405 Patent unless specifically authorized pursuant to the confidential settlement agreement.

In June 2017, Amgen filed four additional lawsuits in the Delaware District Court for infringement of the '405 Patent against: (1) Piramal Healthcare UK Limited (Piramal), (2) Alkem Laboratories Ltd. (Alkem), (3) Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, Lupin), and (4) Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, Macleods). In each lawsuit, all defendants have responded to the complaint denying infringement and seeking a declaration of non-infringement and invalidity of the '405 Patent. Macleods' response also included a counterclaim alleging sham litigation in violation of the Sherman Antitrust Act, which Amgen has denied. On August 15, 2017, the Delaware District Court consolidated the lawsuit filed against Piramal into the existing consolidated case. The Delaware District Court consolidated the lawsuits filed against Alkem, Lupin and Macleods into a separate single case, *Amgen Inc. v. Alkem et al.,* on December 13, 2017, stayed Macleods' Sherman Antitrust counterclaim pending resolution of the patent claims, and has scheduled trial on the patent claims for April 29, 2019.

In December 2017, Amgen filed four additional lawsuits in the Delaware District Court for infringement of the '405 Patent against (1) Watson Laboratories, Inc. and Actavis Pharma Inc., (2) Teva Pharmaceuticals, USA, Inc., (3) Barr Laboratories, Inc., and (4) Torrent Pharmaceuticals Ltd.

Sensipar® Pediatric Exclusivity Litigation

On May 25, 2017, Amgen filed a lawsuit in the U.S. District Court for the District of Columbia (the D.C. District Court) seeking effectively to reverse the FDA's May 22, 2017 rejection of Amgen's request for pediatric exclusivity for cinacalcet hydrochloride (Sensipar®/Mimpara®). Four companies seeking to market generic versions of Sensipar® were granted leave to intervene, but all but Amneal Pharmaceuticals LLC have subsequently withdrawn from the case. On January 26, 2018, the D.C. District Court granted in part and denied in part the summary judgment motions filed separately by each of the parties and remanded the case to the FDA for the limited purpose of the FDA addressing whether the FDA's denial of pediatric exclusivity in the case is inconsistent with a prior FDA pediatric exclusivity decision on a different drug. The FDA has responded that its denial of pediatric exclusivity for cinacalcet

hydrochloride was appropriate and not inconsistent with its prior decisions. The parties await the court's ruling on the remaining portions of their summary judgment motions.

KYPROLIS® (carfilzomib) ANDA Patent Litigation

Beginning in October 2016, our subsidiary Onyx Therapeutics, Inc. (Onyx Therapeutics), filed four separate lawsuits in the Delaware District Court against: Cipla; Sagent Pharmaceuticals, Inc.; Breckenridge; and Fresenius Kabi, USA LLC, Fresenius

Kabi USA, Inc., Fresenius Pharmaceuticals Holding, Inc., and Fresenius Kabi Oncology Limited; each for infringing U.S. Patent Nos. 7,232,818 (the ’818 Patent); 7,417,042 (the ’042 Patent); 7,491,704 (the ’704 Patent); 7,737,112 (the ’112 Patent); 8,129,346 (the ’346 Patent); 8,207,125 (the ’125 Patent); 8,207,126 (the ’126 Patent); 8,207,127 (the ’127 Patent); and 8,207,297 (the ’297 Patent). By joint stipulation of the parties, Fresenius Pharmaceuticals Holding, Inc. and Fresenius Kabi Oncology Limited were subsequently dismissed from that lawsuit. In October and November 2016, Onyx Therapeutics also filed four separate lawsuits in the Delaware District Court against: MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (collectively, MSN); Dr. Reddy’s; Qilu Pharma, Inc. and Qilu Pharmaceutical Co. Ltd. (collectively, Qilu); and Apotex; each for infringing the ’112 Patent; and a separate lawsuit against InnoPharma, Inc. for infringement of the ’042, ’112 and ’297 Patents. In April 2017, Onyx Therapeutics filed a separate lawsuit in the Delaware District Court against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. for infringement of the ’818, ’042, ’704, ’112, ’346, ’125, ’126, ’127 and ’297 Patents. The Delaware District Court has consolidated these ten lawsuits for purposes of discovery into a single case, *Onyx Therapeutics, Inc. v. CIPLA Ltd., et al.* These ten lawsuits are based on ANDAs that seek approval to market generic versions of KYPROLIS® before expiration of the asserted patent or patents. In each lawsuit, Onyx Therapeutics seeks an order of the Delaware District Court making any FDA approval of the defendant’s ANDA effective no earlier than the expiration of the applicable patents. Responses to the complaints have been filed by all defendants alleging invalidity and, in certain instances, non-infringement of the patents. Trial is scheduled to commence on March 11, 2019.

In August 2017, Onyx Therapeutics filed additional lawsuits in the Delaware District Court against InnoPharma, Inc. for infringement of the ’818, ’704, ’346, ’125, ’126 and ’127 Patents; and against Apotex and Qilu for infringement of the ’818, ’042, ’704, ’346, ’125, ’126, ’127 and ’297 Patents. In each lawsuit, Onyx Therapeutics seeks an order of the Delaware District Court making any FDA approval of the defendant’s ANDA effective no earlier than the expiration of the applicable patents. On September 14, 2017, the Delaware District Court consolidated these three additional lawsuits for purposes of discovery into the existing consolidated case. Responses to these new complaints have been filed by InnoPharma, Inc., Apotex and Qilu alleging invalidity and, in certain instances, non-infringement of the patents.

In September 2017, by joint stipulation of the parties, Teva Pharmaceutical Industries Ltd. was dismissed from the patent infringement lawsuit that was filed in the Delaware District Court in April 2017, leaving Teva Pharmaceuticals USA, Inc. as the remaining defendant in that litigation.

In November 2017, Onyx Therapeutics filed a lawsuit in the Delaware District Court against Aurobindo Pharma USA, Inc. for infringement of the ’818, ’042, ’704, ’112, ’346, ’125, ’126, ’127 and ’297 Patents. In December 2017, Onyx Therapeutics filed additional lawsuits in the Delaware District Court against Dr. Reddy’s for infringement of the ’818, ’042, ’704, ’346, ’125, ’126, ’127 and ’297 Patents, and against MSN for infringement of the ’112 Patent. In January, Onyx Therapeutics filed a lawsuit in the Delaware District Court against Apotex for infringement of the ’818, ’042, ’704, ’112, ’346, ’125, ’126, ’127 and ’297 Patents. In each lawsuit, Onyx Therapeutics seeks an order of the Delaware District Court making any FDA approval of the defendant’s ANDA effective no earlier than the expiration of the applicable patents. Responses to these complaints have been filed by Auobindo Pharma USA, Inc., Dr. Reddy’s, and MSN alleging invalidity and, in certain instances, non-infringement of the patents.

In February 2018, Qilu was dismissed from the applicable lawsuit by joint stipulation of the parties.

NEUPOGEN® (filgrastim)/ Neulasta® (pegfilgrastim) Litigation

Sandoz NEUPOGEN® Patent Litigation

On October 24, 2014, Amgen Inc. and AML (collectively, Amgen) filed a lawsuit in the U.S. District Court for the Northern District of California (the California Northern District Court) against Sandoz Inc., Sandoz International GmbH and Sandoz GmbH (collectively, Sandoz) for infringement of our U.S. Patent No. 6,162,427 (the ’427 Patent) and various state law claims. The lawsuit stems from Sandoz filing an application for FDA licensure of a filgrastim product as biosimilar to NEUPOGEN® under the Biologics Price Competition and Innovation Act (BPCIA), while having deliberately failed to comply with the BPCIA’s disclosure requirement to Amgen as the reference product sponsor. By its complaint, Amgen seeks, among other remedies, an injunction to cease Sandoz’s unauthorized reliance on Amgen’s Biologics License Application (BLA) for filgrastim and an injunction to prevent Sandoz from infringing, or inducing any infringing use of, filgrastim.

On March 19, 2015, the California Northern District Court issued an order dismissing with prejudice Amgen’s state law claims, and entered judgment in favor of Sandoz Inc. on its cross-motion for partial judgment on the pleadings. The order also denied Amgen’s motion for a preliminary injunction, as well as Amgen’s motion for partial

judgment on the pleadings. On a joint motion of the parties, on March 25, 2015, the California Northern District Court entered final judgment on the claims and counterclaims decided by the court's March 19 order. The remaining patent infringement claim, counterclaim and defenses were stayed by the court pending appeal. On March 25, 2015, Amgen appealed both the judgment in favor of Sandoz Inc. and the denial

of Amgen's motion for preliminary injunction to the Federal Circuit Court. On May 5, 2015, the Federal Circuit Court entered an injunction prohibiting Sandoz Inc. from marketing, selling, offering for sale, or importing into the United States Sandoz's FDA-approved Zarxio® biosimilar product until the Federal Circuit Court resolved the appeal.

On July 21, 2015, the Federal Circuit Court affirmed the California Northern District Court's dismissal of Amgen's state law claims concluding that the only remedies available for a biosimilar applicant's failure to provide its BLA by the statutory deadline is to bring a patent infringement claim and seek those patent remedies provided by the statute. The Federal Circuit Court also concluded that a biosimilar applicant must give 180-day advance notice of first commercial marketing after the FDA has licensed the biosimilar product. Accordingly, the Federal Circuit Court entered an order that its previously entered injunction be extended through September 2, 2015 (180 days from Sandoz Inc.'s notice given after FDA approval).

On February 16, 2016, Sandoz filed a petition for certiorari with the U.S. Supreme Court seeking review of the Federal Circuit Court ruling concluding that a biosimilar applicant must give 180-day advance notice of first marketing and that notice can be given only after the FDA has licensed the biosimilar product. On March 21, 2016, Amgen filed a brief in opposition to Sandoz's petition and a conditional cross-petition for certiorari requesting that the U.S. Supreme Court also review the Federal Circuit Court's ruling that the only remedy available when a biosimilar applicant refuses to provide its BLA is to bring a patent infringement claim. On June 12, 2017, the U.S. Supreme Court reversed the Federal Circuit Court ruling that a biosimilar applicant must wait to give the 180-day advance notice of first commercial marketing until after the FDA has licensed the biosimilar product, holding that such notice can be given either before or after the FDA approval. On a second issue, the U.S. Supreme Court vacated the Federal Circuit Court's decision that the only remedy available when a biosimilar applicant refuses to provide its BLA is to bring a patent infringement claim. The U.S. Supreme Court agreed with the Federal Circuit Court that there is no remedy under federal law for failing to make the disclosure but remanded the case to the Federal Circuit Court to determine whether California law would treat noncompliance with such requirement as unlawful and, if so, to determine whether the BPCIA pre-empts any additional remedy available under state law and whether Sandoz forfeited any pre-emption defense. On December 14, 2017, the Federal Circuit Court affirmed the California Northern District Court's dismissal of Amgen's state law claims, holding that the BPCIA pre-empts state law remedies for a biosimilar applicant's failure to comply with the BPCIA's disclosure requirement.

Following the California Northern District Court's September 8, 2015 lift of the stay of the case, the parties continued to litigate the remaining patent infringement claim, counterclaim and defenses. On October 15, 2015, Amgen filed a first supplemental and amended complaint adding to the lawsuit Sandoz's infringement of U.S. Patent No. 8,940,878 (the '878 Patent), which covers methods of purifying proteins. On September 13, 2017, by joint stipulation of the parties, the California Northern District Court dismissed from the case the parties' respective claims and counterclaims related to the '427 Patent. On October 25, 2017, Sandoz filed motions for summary judgment of noninfringement of the '878 Patent and for summary judgment regarding damages. On December 19, 2017, the California Northern District Court granted Sandoz's summary judgment of noninfringement. Sandoz's motion for summary judgment regarding damages was denied as moot. On January 8, 2018, the California Northern District Court entered judgment of noninfringement of the '878 and '427 Patents and dismissed without prejudice Sandoz's counterclaims of invalidity of the '878 and '427 Patents. Amgen filed an appeal of the judgment on February 5, 2018.

Sandoz Neulasta® Patent Litigation

On May 12, 2016, Amgen filed a lawsuit in the California Northern District Court against Sandoz and Lek Pharmaceuticals d.d. for infringement of the '878 Patent and 5,824,784 (the '784 Patent) in accordance with the patent provisions of the BPCIA. The lawsuit stems from Sandoz filing an application for FDA licensure of a pegfilgrastim product as biosimilar to Neulasta®. On June 23, 2016, Sandoz responded to the complaint, denying infringement and seeking judgment that the patents-in-suit are invalid and/or not infringed. On December 7, 2016, by joint stipulation of the parties, the California Northern District Court dismissed from the case all claims and counterclaims related to the '784 Patent. On October 25, 2017, Sandoz filed motions for summary judgment of noninfringement of the '878 Patent and for summary judgment regarding damages. On December 19, 2017, the California Northern District Court granted Sandoz's summary judgment of noninfringement of the '878 Patent. Sandoz's motion for summary judgment regarding damages was denied as moot. On January 8, 2018, the California Northern District Court entered judgment of noninfringement of the '878 Patent and dismissed without prejudice Sandoz's counterclaims of invalidity of the '878 Patent. Amgen filed an appeal of the judgment on February 5, 2018.

Apotex NEUPOGEN®/Neulasta® Patent Litigation

On August 6 and October 2, 2015, Amgen filed two separate lawsuits in the U.S. District Court for the Southern District of Florida (the Florida Southern District Court) against Apotex for infringement of our U.S. Patent Nos.

8,952,138 (the ’138 Patent), the ’784 Patent and the ’427 Patent, in accordance with the patent provisions of the BPCIA and for a declaration that Apotex’s pre-licensure notice of commercial marketing is legally ineffective. These lawsuits stem from Apotex’s submissions of applications for FDA licensure of a pegfilgrastim product as biosimilar to Amgen’s Neulasta®, and a filgrastim product as biosimilar to Amgen’s NEUPOGEN®, respectively. By its complaints, Amgen seeks, among other remedies, an injunction prohibiting Apotex from

infringing the ’138, ’784 and ’427 Patents and enjoining Apotex from commencing commercial marketing of any biosimilar pegfilgrastim product or biosimilar filgrastim product, respectively, until a date that is at least 180 days after Apotex provides legally effective notice to Amgen. Apotex answered the August 6 complaint on October 5, 2015, denying patent infringement, alleging that the patents are invalid, alleging sham litigation in violation of the Sherman Antitrust Act, seeking a declaration that the ’138 Patent is unenforceable for patent misuse and seeking a declaration on the interpretation of the BPCIA commercial notice provision. On November 3, 2015, the Florida Southern District Court consolidated the two lawsuits into a single case.

On December 9, 2015, the Florida Southern District Court granted Amgen’s motion for preliminary injunction prohibiting Apotex from commercializing its biosimilar pegfilgrastim product until a date that is at least 180 days after Apotex provides legally effective commercial notice to Amgen. On July 5, 2016, the Federal Circuit Court affirmed the Florida Southern District Court injunction, holding that the 180-day notice of commercial marketing is mandatory under the BPCIA and can be given only post-FDA licensure of the biosimilar product. On September 9, 2016, Apotex petitioned the U.S. Supreme Court for certiorari, seeking review of the Federal Circuit Court holding. On December 12, 2016, the U.S. Supreme Court denied Apotex’s petition for certiorari.

On June 15, 2016, the Florida Southern District Court dismissed without prejudice all claims and counterclaims related to the ’427 and ’784 Patents on the parties’ joint stipulation of dismissal. In a separate order that same day, the Florida Southern District Court also dismissed without prejudice all counterclaims related to unlawful monopolization in violation of the Sherman Antitrust Act on the parties’ joint stipulation of dismissal. On June 24, 2016, the Florida Southern District Court issued a further claim construction decision granting the motion for summary judgment of no literal infringement of the ’138 Patent filed by Apotex and denying the motion with respect to no infringement under the doctrine of equivalents. On July 11, 2016, trial began on infringement of the ’138 Patent and Apotex’s counterclaims and defenses. On September 16, 2016, the Florida Southern District Court entered final judgment that Apotex’s process of manufacturing its filgrastim and pegfilgrastim products do not infringe the ’138 Patent, dismissing without prejudice Apotex’s remaining invalidity counterclaim for patent invalidity, and making permanent the injunction compelling Apotex to provide 180-day advance notice of first commercial marketing of its filgrastim and pegfilgrastim products if and when the FDA approves these products. Amgen appealed and on November 13, 2017, the Federal Circuit Court affirmed the Florida Southern District Court’s judgment.

On February 17, 2017, the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office granted Apotex’s petition to institute an *inter partes* review (IPR) of the ’138 Patent, challenging claims of the ’138 Patent as unpatentable. On May 22, 2017, Amgen filed its response and oral argument was held before the PTAB on December 13, 2017.

Coherus Neulasta® Patent Litigation

On May 10, 2017, Amgen filed a lawsuit in the Delaware District Court against Coherus BioSciences, Inc. (Coherus) for infringement of our U.S. Patent No. 8,273,707 (the ’707 Patent). This lawsuit stems from Coherus’ submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen’s Neulasta® under the BPCIA. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Coherus from infringing the ’707 Patent. On June 1, 2017, Coherus filed a motion to dismiss the complaint as purportedly failing to state a claim of patent infringement. On December 7, 2018, a magistrate judge recommended that the motion be granted with prejudice. Amgen filed objections to the recommendation and awaits a ruling by the court on Coherus’ motion to dismiss. A claim construction hearing is scheduled for June 25, 2018, and trial is scheduled to commence on September 16, 2019.

Mylan Neulasta® Patent Litigation

On September 22, 2017, Amgen Inc. and AML (collectively, Amgen) filed a lawsuit in the District Court for the Western District of Pennsylvania against Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. (collectively, Mylan) for infringement of our ’707 Patent and U.S. Patent No. 9,643,997 (the ’997 Patent). This lawsuit stems from Mylan’s submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen’s Neulasta® under the BPCIA. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Mylan from infringing the ’707 and ’997 Patents. On November 22, 2017, Mylan answered the complaint, denying patent infringement and alleging that the patents are invalid.

ENBREL (etanercept) Litigation

Sandoz ENBREL Patent Litigation

On February 26, 2016, two affiliates of Amgen Inc. (Immunex Corporation and AML (collectively, Amgen)), along with Hoffmann-La Roche Inc. (Roche), filed a lawsuit in U.S. District Court for the District of New Jersey (the

New Jersey District Court) against Sandoz. This lawsuit stems from Sandoz's submission of an application for FDA licensure of an etanercept product as biosimilar to Amgen's ENBREL. Amgen and Roche have asserted infringement of five patents: U.S. Patent Nos. 8,063,182 (the '182 Patent); 8,163,522 (the '552 Patent); 7,915,225; 8,119,605; and 8,722,631 (the '631 Patent). By their complaint, Amgen and Roche seek an injunction to prohibit Sandoz from commercializing its biosimilar etanercept product in the United States prior to

the expiry of such patents. Responses have been filed by all Sandoz defendants denying infringement and/or asserting that the patents at issue are invalid. On August 11, 2016, and subject to the terms of a confidential stipulation, the New Jersey District Court entered a preliminary injunction prohibiting Sandoz from making, using, importing, selling or offering for sale Sandoz's etanercept product. Trial is scheduled to start on April 17, 2018. On August 30, 2016, the FDA approved Sandoz's Erelzi™, a biosimilar to ENBREL.

On September 14, 2017, Amgen filed a motion for summary judgment that Sandoz infringed claim 1 of the '631 Patent and, on October 23, 2017, Sandoz filed its brief in opposition to the motion.

Coherus ENBREL Patent Challenge

On August 4 and September 7, 2017, Coherus filed separate petitions seeking to institute IPR proceedings before the PTAB of the U.S. Patent and Trademark Office to challenge the patentability of each claim of the '522 Patent and the '182 Patent, respectively. Both the '522 Patent and the '182 Patent relate to ENBREL and are exclusively licensed to our subsidiary Immunex Corporation by Roche. Patent owner preliminary responses to the Coherus IPR petition were filed on December 13, 2017 regarding the '522 Patent and on December 15, 2017 regarding the '182 Patent, explaining that Coherus' petitions are without merit and requesting that the PTAB not institute IPR proceedings. The deadlines by which the PTAB is expected to render a decision regarding whether to institute IPR trial proceedings on the '522 Patent and the '182 Patent are March 15 and March 26, 2018, respectively.

Hospira EPOGEN® (epoetin alfa) Patent Litigation

On September 18, 2015, Amgen filed a lawsuit in the Delaware District Court against Hospira, Inc. (Hospira), a subsidiary of Pfizer, for infringement of Amgen's U.S. Patent Nos. 5,856,298 (the '298 Patent) and 5,756,349 (the '349 Patent) in accordance with the patent provisions of the BPCIA and for a declaration that Hospira has failed to comply with certain requirements of the BPCIA. This lawsuit stems from the submission by Hospira under the BPCIA of an application for FDA licensure of an epoetin product as biosimilar to Amgen's EPOGEN®. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Hospira from using or selling infringing cells and/or product manufactured during the '298 or the '349 Patent terms and enjoining Hospira from commencing commercial marketing of any biosimilar epoetin product until a date that is at least 180 days after Hospira provides legally effective notice to Amgen.

On August 19, 2016, Hospira responded to the complaint denying patent infringement and any violation of the BPCIA and seeking judgment that the patents-in-suit are invalid and not infringed by Hospira. On January 23, 2017, the Delaware District Court entered an order construing the claims of the '349 and '298 Patents and holding that two claims of the '298 Patent are invalid for failure to properly narrow the claim on which they depend.

On September 22, 2017, after a five-day trial, the jury returned a verdict finding the '298 Patent valid and infringed by Hospira and the '349 Patent not infringed. The jury awarded Amgen $70 million in damages for Hospira's infringement. On October 23, 2017, Hospira moved for judgment as a matter of law of non-infringement and invalidity of the '298 Patent or, in the alternative, for reduction of the damage award or a new trial on the '298 Patent.

MVASI™ (bevacizumab-awwb) Patent Litigation

On October 6, 2017, Amgen filed a lawsuit in the U.S. District Court for the Central District of California (the California Central District Court) against Genentech, Inc. (Genentech) and City of Hope seeking a declaratory judgment that 27 patents listed by Genentech in the BPCIA exchange are invalid, unenforceable and/or not infringed by MVASI™, Amgen's biosimilar of Avastin® (bevacizumab). On February 2, 2018, the California Central District Court granted Genentech and City of Hope's motion to dismiss for lack of subject matter jurisdiction.

On October 6 and October 18, 2017, Genentech and City of Hope filed separate lawsuits in the Delaware District Court alleging Amgen's infringement of (i) 24 of the 27 patents listed by Genentech in the BPCIA exchange and (ii) 25 of the same 27 patents and, in each case, for non-compliance with certain provisions of the BPCIA. On December 6, 2017, Genentech and City of Hope amended their complaints to allege that Amgen will also infringe newly issued U.S. Patent No. 9,795,672. On January 22, 2018, Amgen's motions to transfer the two Delaware lawsuits to the California Central District Court were denied.

State Derivative Litigation

The three state stockholder derivative complaints filed against Amgen, Kevin W. Sharer, George J. Morrow, Dennis M. Fenton, Brian M. McNamee, Roger M. Perlmutter, David Baltimore, Gilbert S. Omenn, Judith C. Pelham, Frederick W. Gluck, Jerry D. Choate, J. Paul Reason, Frank J. Biondi, Jr., Leonard D. Schaeffer, Frank C. Herringer, Richard D. Nanula, Willard H. Dere, Edward V. Fritzky, Franklin P. Johnson, Jr. and Donald B. Rice as defendants

(the State Defendants) on May 1, 2007 (*Larson v. Sharer, et al.*, & *Anderson v. Sharer, et al.*), and August 13, 2007 (*Weil v. Sharer, et al.*) in the Superior Court of the State of California, Ventura County (the Ventura County Superior Court) were consolidated by the Ventura County Superior Court under

one action captioned *Larson v. Sharer, et al*. The consolidated complaint was filed on July 5, 2007. The complaint alleges that the State Defendants breached their fiduciary duties, wasted corporate assets, were unjustly enriched and violated the California Corporations Code. Plaintiffs allege that the State Defendants failed to disclose and/or misrepresented results of Aranesp® clinical studies, marketed both Aranesp® and EPOGEN® for off-label uses and that these actions or inactions caused stockholders to suffer damages. The complaints also allege insider trading by the State Defendants. The plaintiffs seek treble damages based on various causes of action, reformed corporate governance, equitable and/or injunctive relief, restitution, disgorgement of profits, benefits and other compensation, and legal costs.

An amended consolidated complaint was filed on March 13, 2008, adding Anthony Gringeri as a State Defendant and removing the causes of action for insider selling and misappropriation of information, violation of California Corporations Code Section 25402 and violation of California Corporations Code Section 25403. On July 14, 2008, the Ventura County Superior Court dismissed without prejudice the consolidated state derivative class action. On July 24, 2013, the plaintiffs filed an amended complaint asserting additional grounds for the defendants' alleged breaches of fiduciary duty. By stipulation of the parties, the case was stayed pending resolution of the *In re Amgen Inc. Securities Litigation* action. Final settlement by the parties of the *In re Amgen Inc. Securities Litigation* action was approved by the court in October 2016, and on February 10, 2017, the Ventura County Superior Court lifted the stay in *Larson v. Sharer, et al*. On June 2, 2017, plaintiffs filed a third amended complaint with the Ventura County Superior Court in this case (now captioned *Anderson v. Sharer, et. al*), adding Robert A. Bradway, François de Carbonnel, Vance D. Coffman, Robert A. Eckert, Rebecca M. Henderson, Tyler Jacks, and Ronald D. Sugar as additional State Defendants and removing Chris Larson as a plaintiff. The third amended complaint adds additional allegations, including that Amgen engaged in improper marketing with respect to ENBREL, Vectibix®, Sensipar®, and XGEVA®. On July 3, 2017, the State Defendants filed demurrers seeking dismissal of all claims. On November 13, 2017, the Ventura County Superior Court granted the State Defendants' demurrers without leave to amend. On December 20, 2017, the Ventura County Superior Court entered a judgment in favor of the State Defendants and dismissed the matter with prejudice.

U.S. Attorney's Office for the District of Massachusetts—Patient Assistance Investigation

Amgen, together with other companies in our industry, has received inquiries from the U.S. Attorney's Office for the District of Massachusetts relating to support of charitable 501(c)(3) organizations that provide financial assistance to Medicare patients. Amgen is cooperating with this ongoing inquiry.

Commitments

Lease commitments

We lease certain facilities and equipment related primarily to administrative, R&D, sales and marketing activities under noncancelable operating leases that expire through 2043. The following table summarizes the minimum future rental commitments under noncancelable operating leases as of December 31, 2017 (in millions):

	Amount
2018	$ 158
2019	126
2020	116
2021	100
2022	59
Thereafter	91
Total minimum operating lease commitments	$ 650

Included in the table above are future rental commitments for abandoned leases in the amount of $264 million. There were no material charges for lease abandonments related to the restructuring plan that commenced in 2014. See Note 2, Restructuring. We expect to receive total future rental income of $205 million relating to noncancelable subleases of abandoned facilities. Rental expense on operating leases for the years ended December 31, 2017, 2016 and 2015, was $159 million, $134 million and $133 million, respectively.

U.S. repatriation tax commitments

Under the 2017 Tax Act, we will elect to pay the repatriation tax primarily related to our prior indefinitely invested earnings of our foreign operations in eight annual installments beginning in April 2018. See Note 5, Income taxes. As of December 31, 2017, we expect to pay $7.3 billion in repatriation taxes during the following years (in millions):

	Amount
2018	$ 585
2019	585
2020	585
2021	585
2022	585
Thereafter	4,391
Total U.S. repatriation tax commitments	$ 7,316

19. Segment information

We operate in one business segment: human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Enterprise-wide disclosures about product sales; revenues and long-lived assets by geographic area; and revenues from major customers are presented below.

Revenues

Revenues were as follows (in millions):

	Years ended December 31,		
	2017	2016	2015
Product sales:			
ENBREL	$ 5,433	$ 5,965	$ 5,364
Neulasta®	4,534	4,648	4,715
Aranesp®	2,053	2,093	1,951
Prolia®	1,968	1,635	1,312
Sensipar®/Mimpara®	1,718	1,582	1,415
XGEVA®	1,575	1,529	1,405
EPOGEN®	1,096	1,282	1,856
KYPROLIS®	835	692	512
Vectibix®	642	611	549
Nplate®	642	584	525
NEUPOGEN®	549	765	1,049
Repatha®	319	141	10
BLINCYTO®	175	115	77
Other	256	250	204
Total product sales	21,795	21,892	20,944
Other revenues	1,054	1,099	718
Total revenues	$ 22,849	$ 22,991	$ 21,662

Geographic information

Outside the United States, we sell products principally in Europe. The geographic classification of product sales is based on the location of the customer. The geographic classification of all other revenues is based on the domicile of the entity from which the revenues were earned.

Certain geographic information with respect to revenues and long-lived assets (consisting of property, plant and equipment, net) was as follows (in millions):

	Years ended December 31,		
	2017	2016	2015
Revenues:			
United States	$ 18,029	$ 18,326	$ 17,167
Rest of the world (ROW)	4,820	4,665	4,495
Total revenues	$ 22,849	$ 22,991	$ 21,662

	December 31,	
	2017	2016
Long-lived assets:		
United States	$ 2,349	$ 2,328
Puerto Rico	1,527	1,591
ROW	1,113	1,042
Total long-lived assets	$ 4,989	$ 4,961

Major customers

In the United States, we sell primarily to pharmaceutical wholesale distributors that we utilize as the principal means of distributing our products to healthcare providers. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

We had product sales to three customers each accounting for more than 10% of total revenues for each of the years ended December 31, 2017, 2016 and 2015. For the year ended December 31, 2017, on a combined basis, these customers accounted for 81% and 96% of total gross revenues and U.S. gross product sales, respectively, as noted in the following table. Certain information with respect to these customers was as follows (dollar amounts in millions):

	Years ended December 31,		
	2017	2016	2015
AmerisourceBergen Corporation:			
Gross product sales	$ 10,742	$ 10,100	$ 10,038
% of total gross revenues	31 %	31 %	34 %
% of U.S. gross product sales	37 %	38 %	42 %
McKesson Corporation:			
Gross product sales	$ 10,625	$ 9,710	$ 8,766
% of total gross revenues	30 %	30 %	30 %
% of U.S. gross product sales	35 %	34 %	34 %
Cardinal Health, Inc.:			
Gross product sales	$ 7,049	$ 6,520	$ 5,045
% of total gross revenues	20 %	20 %	17 %
% of U.S. gross product sales	24 %	24 %	21 %

As of December 31, 2017 and 2016, amounts due from these three customers each exceeded 10% of gross trade receivables and accounted for 75% and 76%, respectively, of net trade receivables on a combined basis. As of December 31, 2017 and 2016, 14% and 21%, respectively, of trade receivables, net, were due from customers located outside the United States, primarily in Europe. Our total allowance for doubtful accounts as of December 31, 2017 and 2016 was not material.

20. Quarterly financial data (unaudited)

The following tables summarize the Company's unaudited financial data on a quarterly basis. The sum of the quarterly earnings (loss) per share amounts may not equal the amount reported for the full year since per share amounts are computed independently for each quarter and for the full year based on respective weighted-average shares outstanding and dilutive securities.

Quarterly financial data is summarized as follows (in millions, except per share data):

	2017 Quarters ended			
	December 31	September 30	June 30	March 31
Product sales	$ 5,569	$ 5,453	$ 5,574	$ 5,199
Gross profit from product sales	$ 4,510	$ 4,463	$ 4,550	$ 4,203
Net (loss) income	$ (4,264)	$ 2,021	$ 2,151	$ 2,071
(Loss) earnings per share:				
Basic	$ (5.89)	$ 2.78	$ 2.93	$ 2.81
Diluted[1]	$ (5.89)	$ 2.76	$ 2.91	$ 2.79
	2016 Quarters ended			
	December 31	September 30	June 30	March 31
Product sales	$ 5,663	$ 5,516	$ 5,474	$ 5,239
Gross profit from product sales	$ 4,596	$ 4,489	$ 4,424	$ 4,221
Net income	$ 1,935	$ 2,017	$ 1,870	$ 1,900
Earnings per share:				
Basic	$ 2.61	$ 2.70	$ 2.49	$ 2.52
Diluted	$ 2.59	$ 2.68	$ 2.47	$ 2.50

[1] During periods of net loss, diluted loss per share is equal to basic loss per share as the anti-dilutive effect of potential common shares is disregarded.

21. Subsequent event

On October 30, 2017, we announced that we had agreed to acquire the remaining 50% ownership of K-A from Kirin, making K-A a wholly owned subsidiary of Amgen. Under the terms of the agreement, Kirin will receive $780 million for its shares of K-A. Amgen will make additional payments to Kirin upon the occurrence of certain sales (valued by Amgen at approximately $30 million). As sole shareholder of K-A, Amgen will own the product rights and remaining cash held by K-A. License agreements between K-A and Kirin in certain Asian territories, as well as license agreements with J&J, will remain in place. See Note 8, Related party transactions.

The transaction will be accounted for as a business combination and was effective in the first quarter of 2018. Given the timing of the closing of this share transaction, we are currently in the process of valuing the assets acquired and liabilities assumed in the business combination. As a result, we are not yet able to provide the amounts to be recognized as of the share acquisition date for the major classes of assets acquired and liabilities assumed and other related disclosures. We will disclose this and other related information in our Form 10-Q for the quarter ended March 31, 2018.

SCHEDULE II

AMGEN INC.

VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2017, 2016 and 2015

(In millions)

Allowance for doubtful accounts	Balance at beginning of period	Additions charged to costs and expenses	Other additions	Deductions	Balance at end of period
Year ended December 31, 2017	$ 51	$ 4	$ —	$ 4	$ 51
Year ended December 31, 2016	$ 55	$ 11	$ —	$ 15	$ 51
Year ended December 31, 2015	$ 50	$ 18	$ —	$ 13	$ 55