

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

(State or other jurisdiction of incorporation or organization)

95-3540776

(I.R.S. Employer Identification No.)

One Amgen Center Drive

Thousand Oaks

California

(Address of principal executive offices)

91320-1799

(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.

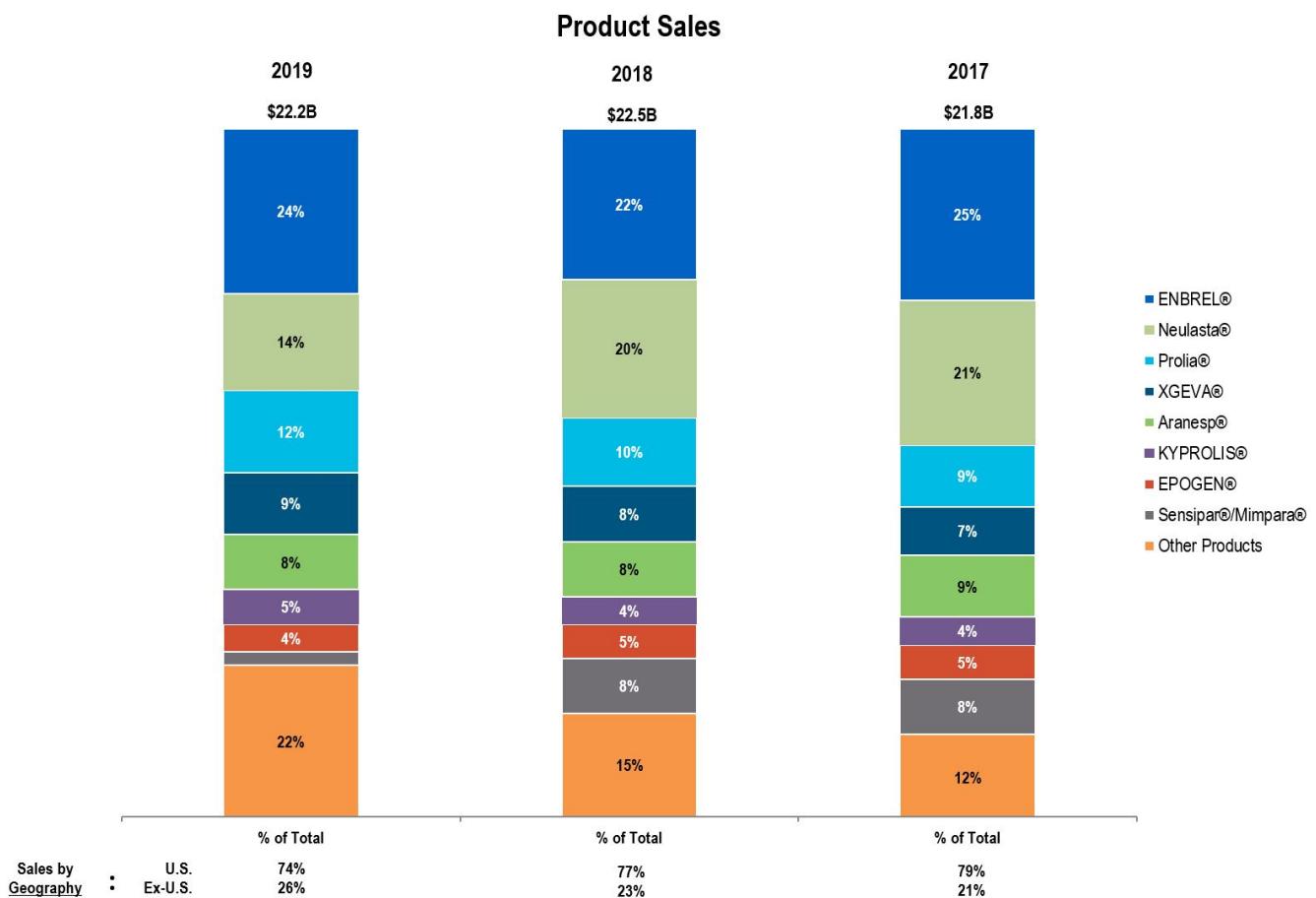
Marketing, Distribution and Selected Marketed Products

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.



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
Aranesp® (darbepoetin alfa)	Europe	RANKL antibodies, including sequences ⁽¹⁾	6/25/2022
	U.S.	Glycosylation analogs of erythropoietin proteins	5/15/2024
	U.S.	Formulation	9/22/2026
Sensipar®/Mimpara® (cinacalcet)	Europe	Calcium receptor-active molecules ⁽¹⁾	10/23/2015
	Europe	Formulation	9/10/2024
	U.S.	Compositions and compounds	12/7/2027
KYPROLIS® (carfilzomib)	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
	U.S.	Thrombopoietic compounds	1/19/2022
Nplate® (romiplostim)	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-aooo)	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
IMLYGIC® (talimogene laherparepvec)	Europe	Methods of treatment	8/10/2035
	U.S.	Compositions	11/23/2025
	U.S.	Method of treatment	3/27/2022
Corlanor® (ivabradine)	Europe	Composition and uses ⁽¹⁾	3/27/2022
	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

Otezla® (apremilast)	Europe	Methods of treatment	4/18/2032
	Europe	Formulation and methods of using formulation	5/11/2031
	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 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
	U.S.	PROCRI ^{®(4)}	Janssen ⁽¹⁾
Aranesp®	U.S.	MIRCERA® ⁽⁵⁾	Galenica Group (Galenica)/F. Hoffmann-La Roche Ltd. (Roche)
	U.S. & Europe	Epoetin alfa biosimilars	Various
	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⁾ PROCRI[®] 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
	Behcet's disease	Acquired from Celgene
Otezla®	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 currently 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 debtor 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 debtor 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:

	Manufacturing	Administrative	Research and/or development	Sales and marketing	Warehouse	Distribution center		Manufacturing	Administrative	Research and/or development	Sales and marketing	Warehouse	Distribution center	
U.S. Location:														
Thousand Oaks, CA*	✓	✓	✓	✓	✓	✓		Brazil	✓	✓	✓	✓	✓	
San Francisco, CA			✓					Canada	✓	✓	✓	✓		
Louisville, KY					✓	✓		China	✓	✓	✓			
Cambridge, MA			✓					Germany	✓	✓	✓			
Woburn, MA	✓				✓			Iceland	✓	✓				
Juncos, Puerto Rico	✓	✓			✓	✓		Ireland	✓	✓				
West Greenwich, RI	✓	✓			✓			Japan	✓	✓	✓	✓		
Tampa, FL		✓						Netherlands	✓	✓	✓	✓	✓	
Other U.S. cities	✓			✓				Singapore	✓	✓				
								Switzerland	✓					
								Turkey	✓	✓	✓	✓	✓	
								United Kingdom	✓	✓	✓	✓	✓	
								Other countries	✓	✓	✓	✓	✓	

* Corporate headquarters

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

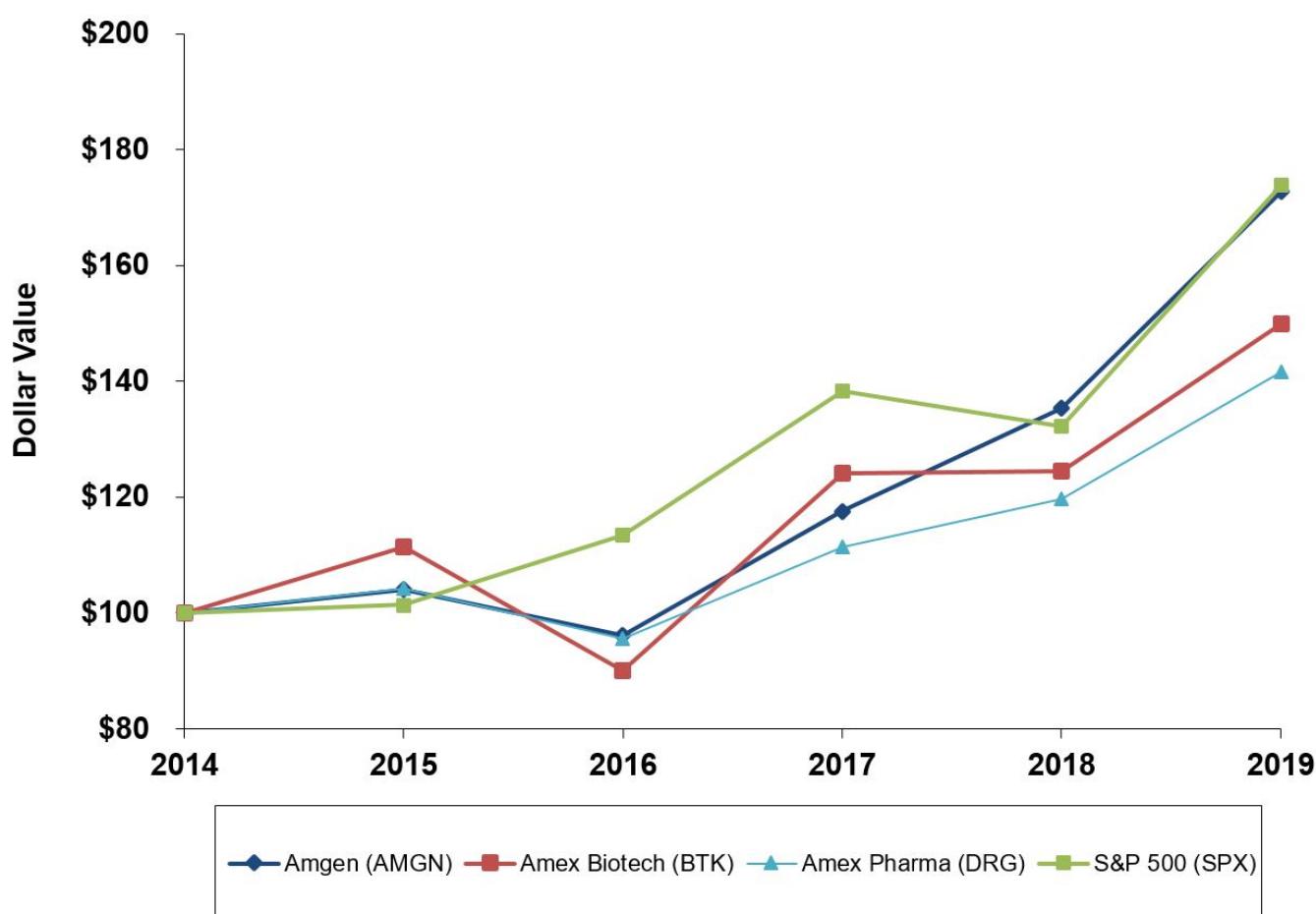
Common stock

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.

Comparison of Five Year Cumulative Total Return of a \$100 Investment on Dec 31, 2014



	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
	<u>5,069,429</u>	<u>\$ 215.10</u>	<u>5,069,429</u>	
January 1 - December 31	<u><u>40,244,414</u></u>	<u><u>\$ 189.85</u></u>	<u><u>40,244,414</u></u>	

⁽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

<u>Consolidated Statements of Income Data:</u>	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

<u>Consolidated Balance Sheets Data:</u>	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			
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	<u>4,959</u>	<u>49 %</u>	<u>3,338</u>	<u>29 %</u>	<u>2,583</u>
Total product sales	<u>\$ 22,204</u>	<u>(1)%</u>	<u>\$ 22,533</u>	<u>3 %</u>	<u>\$ 21,795</u>
Total U.S.	<u>\$ 16,531</u>	<u>(5)%</u>	<u>\$ 17,429</u>	<u>2 %</u>	<u>\$ 17,131</u>
Total ROW	<u>5,673</u>	<u>11 %</u>	<u>5,104</u>	<u>9 %</u>	<u>4,664</u>
Total product sales	<u><u>\$ 22,204</u></u>	<u><u>(1)%</u></u>	<u><u>\$ 22,533</u></u>	<u><u>3 %</u></u>	<u><u>\$ 21,795</u></u>

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	<u>\$ 5,226</u>	<u>4 %</u>	<u>\$ 5,014</u>	<u>(8)%</u>	<u>\$ 5,433</u>

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	<u>\$ 4,959</u>	49 %	<u>\$ 3,338</u>	29 %	<u>\$ 2,583</u>
Total U.S. — other products	<u>\$ 2,907</u>	49 %	<u>\$ 1,947</u>	37 %	<u>\$ 1,419</u>
Total ROW — other products	<u>2,052</u>	48 %	<u>1,391</u>	20 %	<u>1,164</u>
Total other product sales	<u><u>\$ 4,959</u></u>	49 %	<u><u>\$ 3,338</u></u>	29 %	<u><u>\$ 2,583</u></u>

* 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	<u>\$ 4,116</u>	<u>\$ 3,737</u>	<u>\$ 3,562</u>

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 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, 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):

Contractual obligations	Payments due by period as of December 31, 2019					Years 6 and beyond
	Total	Year 1	Years 2 and 3	Years 4 and 5		
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	<u>\$ 3,165</u>	<u>\$ 559</u>	<u>\$ 156</u>	<u>\$ 3,880</u>

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)	(b)	(c)
	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⁾	10,233,680	\$ 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](#)

- 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.)

- 10.14+* [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.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)

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

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	<u>241</u>	<u>(81)</u>	<u>(208)</u>
Comprehensive income	<u>\$ 8,083</u>	<u>\$ 8,313</u>	<u>\$ 1,771</u>

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	<u>591.4</u>	<u>\$ 31,531</u>	<u>\$ (21,330)</u>	<u>\$ (528)</u>	<u>\$ 9,673</u>

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.

AMGEN INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019

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)	<u>\$ 13,440</u>
<u>Intangible assets:</u>	
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	<u>\$ 13,440</u>

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 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	<u>\$ 18,029</u>	<u>\$ 4,820</u>	<u>\$ 22,849</u>

⁽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	<u>1,600</u>	<u>1,514</u>	<u>8,895</u>
Deferred (benefit) provision:			
Federal	(276)	(317)	(1,120)
State	(22)	(7)	—
Foreign	(6)	(39)	(157)
Total deferred (benefit) provision	<u>(304)</u>	<u>(363)</u>	<u>(1,277)</u>
Total provision for income taxes	<u>\$ 1,296</u>	<u>\$ 1,151</u>	<u>\$ 7,618</u>

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	<u>1,787</u>	<u>1,692</u>
Valuation allowance	(517)	(509)
Net deferred income tax assets	<u>1,270</u>	<u>1,183</u>
Deferred income tax liabilities:		
Acquired intangible assets	(1,288)	(1,509)
Debt	(210)	(184)
Other	(286)	(267)
Total deferred income tax liabilities	<u>(1,784)</u>	<u>(1,960)</u>
Total deferred income taxes, net	<u>\$ (514)</u>	<u>\$ (777)</u>

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	<u>\$ 3,287</u>	<u>\$ 3,061</u>	<u>\$ 2,953</u>

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	<u>14.2 %</u>	<u>12.1 %</u>	<u>79.4 %</u>

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			
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	<u>\$ 8,206</u>	<u>\$ 28</u>	<u>\$ —</u>	<u>\$ 8,234</u>

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	<u>\$ 29,064</u>	<u>\$ 1</u>	<u>\$ (341)</u>	<u>\$ 28,724</u>

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,	
	2019	2018
Cash and cash equivalents	\$ 5,360	\$ 6,365
Marketable securities	2,874	22,359
Total available-for-sale investments	<u>\$ 8,234</u>	<u>\$ 28,724</u>

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):

Contractual maturities	December 31,	
	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	<u>\$ 8,234</u>	<u>\$ 28,724</u>

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):

Types of securities as of December 31, 2018	Less than 12 months		12 months or more	
	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	<u>\$ 3,584</u>	<u>\$ 2,940</u>

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		<u>\$ 4,928</u>	<u>\$ 4,958</u>

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	<u>\$ 4,928</u>	<u>\$ 4,958</u>

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	<u><u>\$ 528</u></u>

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	<u><u>\$ 171</u></u>

(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

⁽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. These 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):

Notes	Effective interest rates	December 31,	
		2019	2018
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	<u>(529)</u>	<u>(6)</u>	<u>(144)</u>	<u>—</u>	<u>(679)</u>
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	<u>(670)</u>	<u>241</u>	<u>(338)</u>	<u>(2)</u>	<u>(769)</u>
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	<u>\$ (718)</u>	<u>\$ 175</u>	<u>\$ 22</u>	<u>\$ (7)</u>	<u>\$ (528)</u>

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,			Consolidated Statements of Income locations
	2019	2018	2017	
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
	<u><u>\$ 165</u></u>	<u><u>\$ (207)</u></u>	<u><u>\$ 412</u></u>	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
	<u><u>\$ 42</u></u>	<u><u>\$ (362)</u></u>	<u><u>\$ (49)</u></u>	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

	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Fair value measurement as of December 31, 2018, using:				
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):

Hedged notes	Foreign currency		U.S. dollars	
	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):

Derivatives in cash flow hedging relationships	Years ended December 31,		
	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):

Consolidated Balance Sheets locations	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,	
	2019	2018	2019	2018
Current portion of long-term debt	\$ 903	\$ 2,396	\$ 4	\$ (3)
Long-term debt	\$ 8,814	\$ 9,361	\$ 292	\$ (50)

(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):

December 31, 2019	Derivative assets		Derivative liabilities	
	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	

December 31, 2018	Derivative assets		Derivative liabilities	
	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); Princeton Pharmaceutical Inc. (Princeton); 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, Princeton, 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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