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, 2020

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

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

(805) 447-1000

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol (s)	Name of each exchange on which registered
Common stock, $0.0001 par value	**AMGN**	**The Nasdaq Stock Market LLC**
1.250% Senior Notes Due 2022	**AMGN22**	**The Nasdaq Stock Market LLC**
2.00% Senior Notes Due 2026	**AMGN26**	**The Nasdaq Stock Market LLC**

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

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

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

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

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

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

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $138,056,968,288 as of June 30, 2020.(A)

(A) Excludes 1,045,777 shares of common stock held by directors and executive officers, and any stockholders whose ownership exceeds ten percent of the shares outstanding, at June 30, 2020. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

577,566,383

(Number of shares of common stock outstanding as of February 3, 2021)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2021 Annual Meeting of Stockholders to be held May 18, 2021, are incorporated by reference into Part III of this annual report.

INDEX

PART I

Item 1. BUSINESS

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

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

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

Significant Developments

Following is a summary of significant developments affecting our business that have occurred and that we have reported since the filing of our Annual Report on Form 10-K for the year ended December 31, 2019.

COVID-19 pandemic

A novel strain of coronavirus (SARS-CoV-2, or severe acute respiratory syndrome coronavirus 2, causing coronavirus disease 19, or COVID-19) was declared a global pandemic by the World Health Organization (WHO) on March 11, 2020. Since the first quarter of 2020 and continuing into 2021, we have seen some impact of the pandemic to our operations. We continue to monitor and respond as the pandemic evolves to ensure the continued development, manufacture and distribution of our medicines. For further discussion, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview, Selected Financial Information and Results of Operations. For a discussion of the risks presented by the COVID-19 pandemic to our results, see Risk Factors in Item 1A. Also see the remainder of Item 1. Business for discussion of pandemic-related impacts to our overall business.

Products/Pipeline

Oncology/Hematology

KYPROLIS® (carfilzomib)

- In August 2020, we announced that the U.S. Food and Drug Administration (FDA) had approved the expansion of the KYPROLIS® U.S. prescribing information to include its use in combination with DARZALEX® (daratumumab) plus dexamethasone in two dosing regimens—once weekly and twice weekly—for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three previous lines of therapy.

Sotorasib (formerly AMG 510)

- In September 2020, we announced updated phase 1 data evaluating sotorasib in 129 patients across multiple advanced solid tumors with Kirsten rat sarcoma viral oncogene homolog (*KRAS) G12C* mutation, which were published in the New England Journal of Medicine. Data from 59 patients with advanced non-small cell lung cancer (NSCLC) were also featured in an oral presentation at a September 2020 medical conference. In the patients with advanced NSCLC who were treated with the 960 mg daily dose, the confirmed objective response rate (ORR) was 35.3%. Across all dose levels, the confirmed ORR was 32.2%, with median duration of response of 10.9 months and median progression-free survival (PFS) of 6.3 months; 10 of 19 responders were still in response as of the data cutoff.
- In October 2020, we announced top-line phase 2 results in 126 patients with *KRAS G12C*-mutant advanced NSCLC. Sotorasib demonstrated an ORR (primary endpoint) consistent with previously reported phase 1 data in patients taking the 960 mg daily dose. Other measures of efficacy, including duration of response, were promising, and more than half of the responders were still on treatment and continuing to respond as of the data cutoff date. The results of this phase 2 study are potentially registrational, and a phase 3 confirmatory study comparing sotorasib to docetaxel is currently recruiting patients with *KRAS G12C*-mutant advanced NSCLC.

- In December 2020, we announced that the FDA had granted Breakthrough Therapy designation for our investigational KRAS^{G12C} inhibitor, sotorasib, for the treatment of patients with locally advanced or metastatic NSCLC with *KRAS G12C* mutation, as determined by an FDA-approved test, following at least one prior systemic therapy. Following this announcement, we submitted a New Drug Application (NDA) to the FDA. The sotorasib NDA is being reviewed by the FDA's Real-Time Oncology Review (RTOR) pilot program, which aims to explore a more efficient review process that ensures safe and effective treatments are made available to patients as early as possible. Later in December, we also submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA).
- In January 2021, we announced results from the phase 2 cohort of the clinical study evaluating sotorasib in 126 patients with *KRAS G12C*-mutant advanced NSCLC. Sotorasib demonstrated a confirmed ORR and disease control rate of 37.1% and 80.6%, respectively, a median duration of response of 10 months and median progression-free survival of 6.8 months. In addition, sotorasib was granted Breakthrough Therapy designation by the Center for Drug Evaluation of the National Medical Products Administration in China.

RIABNI™ (rituximab-arrx) (formerly ABP 798)

- In December 2020, we announced that the FDA had approved RIABNI™, a biosimilar to Rituxan® (rituximab), for the treatment of adult patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, granulomatosis with polyangiitis (Wegener's granulomatosis) and microscopic polyangiitis. RIABNI™ launched in the United States in January 2021.

Inflammation

Otezla® (apremilast)

- In May 2020, we announced positive top-line results from a phase 3 study to assess the efficacy of Otezla® in adults with mild-to-moderate plaque psoriasis. The study showed that oral Otezla® 30 mg twice daily achieved a statistically significant improvement, compared with placebo, in the primary endpoint of the static Physician's Global Assessment (sPGA) response (defined as an sPGA score of clear (0) or almost clear (1) with at least a 2-point reduction from baseline) at week 16.

Enbrel® (etanercept)

- In July 2020, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment by the U.S. District Court for the District of New Jersey upholding the validity of the two patents that describe and claim ENBREL and methods for making it. See Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Tezepelumab

- In November 2020, we and AstraZeneca plc (AstraZeneca) announced positive top-line results from the registrational phase 3 NAVIGATOR trial in adults and adolescents with severe uncontrolled asthma. The trial met the primary endpoint with tezepelumab added to standard of care (SoC), demonstrating a statistically significant and clinically meaningful reduction compared with placebo plus SoC in the annualized asthma exacerbation rate (AAER) over 52 weeks in the overall patient population. SoC consisted of medium- or high-dose inhaled corticosteroids (ICS) plus at least one additional controller medication with or without oral corticosteroids (OCS). We expect to submit results of this study to regulators in 2021.
- In December 2020, we and AstraZeneca announced that the SOURCE trial had not met the primary endpoint of a statistically significant reduction in the daily OCS dose, without loss of asthma control, with tezepelumab compared to placebo. The results of this trial have no impact on our submission plans.

Cardiovascular

Omecamtiv mecarbil

- In November 2020, based on results of the omecamtiv mecarbil phase 3 trial, we provided notice to Cytokinetics, Incorporated (Cytokinetics) of termination of our collaboration and our intention to transition to them the development and commercialization rights for omecamtiv mecarbil and AMG 594.

Establishment of wholly owned affiliate in Japan

- In April 2020, we completed our purchase from Astellas of the remaining shares of Amgen Astellas BioPharma K.K. (AABP), a joint venture between Amgen and Astellas established in 2013. AABP, now a wholly owned Amgen affiliate in Japan and renamed Amgen K.K., has enabled us to build a strong presence in Japan as we continue to advance treatments for serious illnesses. The purchase did not have a material impact to our consolidated financial statements.

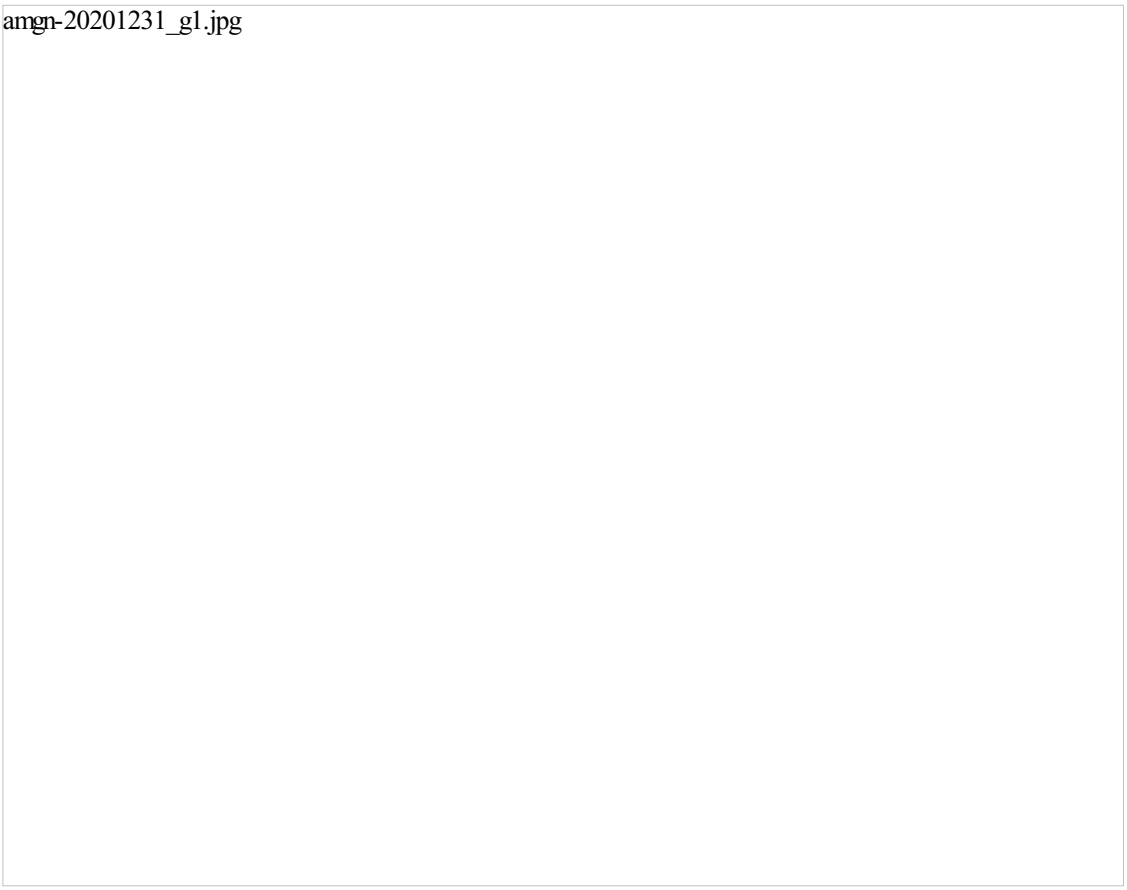
Marketing, Distribution and Selected Marketed Products

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

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

Our product sales to three large wholesalers, AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc., each individually accounted for more than 10% of total revenues for each of the years 2020, 2019 and 2018. On a combined basis, these wholesalers accounted for 83%, 81% and 84% of worldwide gross revenues for 2020, 2019 and 2018, respectively. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

Our products are marketed around the world, with the United States being our largest market. The following chart shows our product sales by principal product, and the table below (dollar amounts in millions) shows product sales by geography for the years 2020, 2019 and 2018.



	2020		2019		2018	
Product Sales by Geography:						
U.S.	$ 17,985	74 %	$ 16,531	74 %	$ 17,429	77 %
Ex-U.S.	6,255	26 %	5,673	26 %	5,104	23 %
Total	$ 24,240	100 %	$ 22,204	100 %	$ 22,533	100 %

ENBREL

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

Prolia® (denosumab)

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

Neulasta® (pegfilgrastim)

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

Otezla®

We market Otezla®, a small molecule that inhibits phosphodiesterase 4 (PDE4), primarily in the United States and Europe. Otezla® was acquired from Bristol-Myers Squibb Company (BMS) in November 2019, post their acquisition of Celgene Corporation (Celgene). Otezla® is an oral therapy approved for the treatment of adult patients with moderate-to-severe plaque psoriasis for whom phototherapy or systemic therapy is appropriate, patients with active psoriatic arthritis and patients with oral ulcers associated with Behçet's disease. In Europe, Otezla® is approved for second-line use in the treatment of psoriatic arthritis and psoriasis.

XGEVA®

We market XGEVA® primarily in the United States and Europe. XGEVA® was launched in 2010 and is used primarily in the indication for prevention of skeletal-related events (SREs) (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumors and multiple myeloma.

Aranesp® (darbepoetin alfa)

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

KYPROLIS®

We market KYPROLIS® primarily in the United States and Europe. KYPROLIS® was launched in 2012 and is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. It is also approved as a single agent for patients with relapsed or refractory multiple myeloma who have received one or more previous therapies. In September 2019, the CANDOR phase 3 study of KYPROLIS® in combination with dexamethasone and DARZALEX® (daratumumab) met its primary endpoint of PFS in patients with relapsed or refractory multiple myeloma. In August 2020, the FDA approved the expansion of the KYPROLIS® U.S. prescribing information to include its use in combination with dexamethasone and DARZALEX®.

Repatha® (evolocumab)

We market Repatha®, a proprotein convertase subtilisin/kexin type 9 (PCSK9), primarily in the United States and Europe. Repatha® was launched in 2015 and is indicated to reduce the risks of myocardial infarction, stroke and coronary revascularization in adults with established cardiovascular (CV) disease.

Other Marketed Products

We also market a number of other products in various markets worldwide, including Nplate® (romiplostim), Vectibix® (panitumumab), MVASI® (bevacizumab-awwb), Parsabiv® (etelcalcetide), EPOGEN® (epoetin alfa), KANJINTI® (trastuzumab-anns), BLINCYTO® (blinatumomab), Aimovig® (erenumab-aooe), EVENITY® (romosozumab-aqqg), AMGEVITA™ (adalimumab), Sensipar®/Mimpara® (cinacalcet), NEUPOGEN® (filgrastim), IMLYGIC® (talimogene laherparepvec), Corlanor® (ivabradine) and AVSOLA® (infliximab-axxq).

Patents

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

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

Product	Territory	General subject matter	Expiration
Enbrel® (etanercept)	U.S.	Methods of treatment using aqueous formulations	6/8/2023
	U.S.	Formulations	10/19/2037
	U.S.	Fusion protein and pharmaceutical compositions	11/22/2028
	U.S.	DNA encoding fusion protein and methods of making fusion protein	4/24/2029
Prolia®/XGEVA® (denosumab)	U.S.	RANKL antibodies	9/17/2021
	U.S.	Methods of treatment	6/25/2022
	U.S.	Nucleic acids encoding RANKL antibodies and methods of producing RANKL antibodies	11/30/2023
	U.S.	RANKL antibodies, including sequences	2/19/2025
	Europe	RANKL antibodies, including epitope binding	2/23/2021
	Europe	RANKL antibodies, including sequences(1)	6/25/2022
Otezla® (apremilast)	U.S.	Compositions and compounds	2/16/2028
	U.S.	Crystalline form	12/9/2023
	U.S.	Methods of treatment	5/29/2034
	Europe	Compositions, compounds and methods of treatment(1)	3/20/2023
	Europe	Formulation	12/26/2032
Aranesp® (darbepoetin alfa)	U.S.	Glycosylation analogs of erythropoietin proteins	5/15/2024
KYPROLIS® (carfilzomib)	U.S.	Compositions and compounds	12/7/2027
	U.S.	Methods of treatment	4/14/2025
	U.S.	Methods of making	5/8/2033
	Europe	Compositions, compounds and methods of treatment(1)	12/7/2025
Repatha® (evolocumab)	U.S.	Antibodies(2)	10/25/2029
	U.S.	Methods of treatment	10/8/2030
	Europe	Compositions(1)	8/22/2028
	Europe	Methods of treatment	5/10/2032
	Europe	Formulation	5/3/2033
Nplate® (romiplostim)	U.S.	Thrombopoietic compounds	1/19/2022
	U.S.	Formulation	2/12/2028
	Europe	Thrombopoietic compounds(1)	10/22/2019
	Europe	Formulation	4/20/2027
Vectibix® (panitumumab)	Europe	Human monoclonal antibodies to epidermal growth factor receptor(1)	5/5/2018
Parsabiv® (etelcalcetide)	U.S.	Compound and pharmaceutical composition	2/7/2031
	U.S.	Formulation	6/27/2034
	U.S.	Methods of making	8/9/2035
	Europe	Compound and pharmaceutical composition(1)	7/29/2030
	Europe	Formulation	6/27/2034
BLINCYTO® (blinatumomab)	U.S.	Pharmaceutical compositions and bifunctional polypeptides	4/6/2030
	U.S.	Method of administration	9/28/2027
	Europe	Bifunctional polypeptides(1)	11/26/2024
	Europe	Method of administration	11/6/2029
Aimovig® (erenumab-aooe)	U.S.	CGRP receptor antibodies(2)	11/9/2031
	U.S.	Methods of treatment	4/22/2036
	Europe	CGRP receptor antibodies(1)	12/18/2029
	Europe	Methods of treatment	8/10/2035
EVENITY® (romosozumab-aqqg)	U.S.	Antibodies(2)	4/25/2026
	U.S.	Methods of treatment(2)	1/11/2029
	U.S.	Formulation and methods of using formulation	5/11/2031
	Europe	Antibodies(1)	4/28/2026
	Europe	Methods of treatment	4/18/2032
	Europe	Formulation and methods of using formulation	5/11/2031
IMLYGIC® (talimogene laherparepvec)	U.S.	Compositions	11/23/2025
	U.S.	Method of treatment	3/27/2022
	Europe	Composition and uses(1)	3/27/2022

CGRP = calcitonin gene-related peptide, RANKL = receptor activator of nuclear factor kappa-B ligand

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

- denosumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2025
- carfilzomib — France, Germany, Italy and Spain, expiring in 2030
- romiplostim — France, Germany, Italy, Spain and the United Kingdom, expiring in 2024
- panitumumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2022
- evolocumab — France and Spain, expiring in 2030
- etelcalcetide — France and Italy, expiring in 2031
- blinatumomab — France, Italy and Spain, expiring in 2029
- erenumab — France, Italy and Spain, expiring in 2033
- talimogene laherparepvec — Spain, expiring in 2026; France, Germany, Italy and the United Kingdom, expiring in 2027
- romosozumab — Italy, expiring in 2031
- apremilast — Italy and Spain, expiring in 2028

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

Competition

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

Certain of the existing patents on our principal products have expired, and we face new and increasing competition, including from biosimilars and generics. A biosimilar is another version of a biological product for which marketing approval is sought or has been obtained based on a demonstration that it is "highly similar" to the original reference product. We expect that the adverse impact on our originator-product sales from biosimilar competition will reflect current trends and actual results given similar conditions. We also believe that when multiple biosimilar versions of one of our originator products get approved and launched, competition could intensify more rapidly, leading to net price declines for both reference and biosimilar products, resulting in a greater impact on our products' sales. In the United States, companies have now launched biosimilar versions of EPOGEN®, NEUPOGEN® and Neulasta® and have approved biosimilars for ENBREL. See also Government Regulation—Regulation in the United States—Approval of Biosimilars. Although we expect competitor biosimilars to compete on price, we believe many patients, providers and payers will continue to place high value on the reputation, reliability and safety of our products. As additional biosimilar competitors come to market, we will leverage our global experience versus both branded and biosimilar competition.

We also have our own biosimilar products both in the United States and outside of U.S. markets that are competing against branded and biosimilar versions of our competitors' products. In 2019, Amgen launched MVASI®, a biosimilar to Avastin® (bevacizumab), and KANJINTI®, a biosimilar to Herceptin® (trastuzumab), in the United States; and AMGEVITA™, a biosimilar to Humira® (adalimumab) in Europe. We have also received FDA approval for AMJEVITA™ (adalimumab-atto), a biosimilar to Humira®. In 2020, we launched AVSOLA®, a biosimilar to Remicade® (infliximab), and in January 2021, we launched RIABNI™, a biosimilar for Rituxan® (rituximab). We expect additional biosimilar competition against both our branded and biosimilar products in the future across all markets.

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

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

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

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

* Approved biosimilars available.

† Approved biosimilars available in Europe.

(1) A subsidiary of Johnson & Johnson (J&J).

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

(3) Dermatology only.

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

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

(6) A subsidiary of Takeda Pharmaceutical Company Limited.

(7) A subsidiary of BMS.

Reimbursement

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

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

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

In addition to market actions taken by private and government payers in the United States, policy makers from both of the major U.S. political parties are pursuing policies to lower drug costs. Potential policies cover a wide range of areas, including allowing the importation of drugs from other countries; instituting international reference pricing (IRP) schemes, which would set the prices of certain drugs based on those available in other countries; establishing caps on price increases based on inflation metrics; increasing transparency on drug pricing; and using third-party value assessments to determine drug prices. Examples of such policies include the previous Administration's November 2020 interim final rule, which attempts to institute most favored nation (MFN) IRP in Medicare Part B and final rule instituting rebate reform in Medicare Part D. Both of these rules are being challenged in court and therefore have not yet been implemented. The direction of drug pricing policy reforms remains unclear at this time.

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

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

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

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

Manufacturing, Distribution and Raw Materials

Manufacturing

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

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

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

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

Distribution

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

Other

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

Manufacturing Initiatives

We have multiple ongoing initiatives that are designed to extend our manufacturing advantage by optimizing our manufacturing network and/or by mitigating risks while continuing to ensure adequate supply of our products.

For example, our licensed next-generation biomanufacturing plant operating in Singapore incorporates multiple innovative technologies into a single facility and was built in half the construction time and at approximately half the operating cost of a traditional plant. Next-generation biomanufacturing plants require smaller manufacturing footprints and offer greater environmental benefits, including reduced consumption of water and energy and lower levels of carbon emissions. Within such plants, the equipment is portable and smaller, and some components are disposable, which provides greater flexibility and speed when manufacturing different medicines simultaneously. This eliminates the otherwise costly and complex retrofitting inherent in standard plants and enables Amgen to respond to changing demands for its medicines with increased agility, ultimately increasing the speed at which a medicine can become available for patients. The Singapore site also has a plant that has been approved to produce small molecule drugs for commercial manufacturing.

In July 2018, we broke ground for our newest next-generation biomanufacturing plant at our West Greenwich, Rhode Island, campus. Construction on this new plant, the first of its kind in the United States, is complete. Upon approval by the FDA and global regulatory authorities, this plant will expand our capacity to manufacture certain products for U.S. and global markets.

In 2019, we initiated projects to expand our manufacturing capabilities in Thousand Oaks, California, as well as at contract manufacturers. These investments will initially support clinical manufacturing but in the future may also be leveraged for commercial manufacturing.

In September 2020, we entered into an arrangement with Lilly to manufacture Lilly's potential COVID-19 therapies. For 2021—and, potentially, through 2022—we expect to allocate a portion of our manufacturing capacity to support this production. Additionally, starting in 2021, we will initiate projects that will expand our manufacturing capacity to enable supply of products and product candidates. These projects will employ new technologies that are being developed by Amgen that are anticipated to allow further optimization of our manufacturing network and processes.

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

Raw Materials and Medical Devices

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

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

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

Government Regulation

Regulation by government authorities in the United States and other countries is a significant factor in the production and marketing of our products and our ongoing R&D activities. To clinically test, manufacture and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. Compliance with these standards is complex, and failure to comply with any of these standards can result in significant implications. See Item 1A. Risk Factors for a discussion of factors, including global regulatory implications, that can adversely impact our development and marketing of commercial products.

Regulation in the United States

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

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

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

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

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

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

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

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

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

Regulation outside the United States

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

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

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

As a result of the United Kingdom's decision to leave the EU, the EMA in March 2019 relocated to Amsterdam. The United Kingdom officially left the EU in January 2020, and in December 2020, a new trade deal was agreed that starts to clarify how U.K. medicines will be independently supervised and where continued collaborations and recognitions can be expected. Amgen continues to monitor future negotiations to ensure no interruption in the supervision, regulation or supply of medicines in the United Kingdom and Europe.

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

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

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

Postapproval Phase

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

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

Other Regulation

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

In 2012, Amgen entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health & Human Services (HHS), which was formally closed out in August 2018. On April 25, 2019, we entered into a settlement agreement with the U.S. Department of Justice (DOJ) and the OIG of the HHS to settle certain allegations related to our support of independent charitable organizations that provide patients with financial assistance to access their medicines. Additionally, we entered into a corporate integrity agreement that requires us to maintain a corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that in the future, our practices might be further challenged under antikickback or similar laws.

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

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

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

Research and Development and Selected Product Candidates

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

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

In response to the COVID-19 pandemic, we managed our clinical development on a case-by-case basis. Patients who were already enrolled in studies continued to receive study drug, including through direct-to-patient shipments. For studies that had the potential for significant benefit in a serious or life-threatening condition and when site resources enabled new patients to be enrolled safely and monitored closely, we continued enrollment. For clinical trials experiencing uncertainty with regard to the trial sites' ability to ensure subject safety or data integrity at that time, we temporarily paused enrollment. We remain focused on supporting our active clinical sites in providing care for these patients and providing investigational drug supply. To date, the majority of clinical trials that were paused at the onset of the pandemic to ensure subject safety or data integrity have resumed. Study enrollments were affected the most in the second quarter of 2020 and by the end of the year resumed to prepandemic levels, although COVID-19 infection rates and related vaccination activities may impact future patient enrollment. We continuously monitor and reevaluate the status of studies, pausing when uncertainty arises with regard to the trial sites' ability to ensure safety or data integrity. We remain focused on supporting our active clinical sites in providing care for these patients and in providing investigational drug supply. In addition, our R&D organization is supporting efforts to combat the COVID-19 pandemic in a number of ways, including by (i) working to support production of therapeutic antibodies that could diminish the impact of COVID-19 on patients, (ii) joining a public–private partnership between leading companies in our industry and U.S. government health agencies to develop a strategy for a coordinated research response and (iii) participating in platform studies to investigate treatments in adult patients hospitalized with severe COVID-19 infections.

For the years ended December 31, 2020, 2019 and 2018, our R&D expenses were $4.2 billion, $4.1 billion and $3.7 billion, respectively.

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

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

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

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

The following table shows a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 2, 2021, unless otherwise indicated. Additional product candidate information can be found on our website at www.amgen.com. (The website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.) The information in this section does not include other, nonregistrational clinical trials that we may conduct for purposes other than for submission to regulatory agencies for their approval of a new product indication.

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

Molecule	Disease/condition
Phase 3 programs	
EVENITY®	Male osteoporosis
KYPROLIS®	Weekly dosing for relapsed multiple myeloma
Nplate®	Chemotherapy-induced thrombocytopenia
Otezla®	COVID-19
	Genital psoriasis
	Mild-to-moderate psoriasis
Repatha®	Cardiovascular disease
RIABNI™	Rheumatoid arthritis
Sotorasib	NSCLC with *KRAS G12C* mutations
Tezepelumab	Severe asthma
ABP 654	Psoriasis, psoriatic arthritis and Crohn's disease
ABP 938	Neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy
ABP 959	Paroxysmal nocturnal hemoglobinuria (PNH)
Phase 2 programs	
Olpasiran (formerly AMG 890)	Cardiovascular disease
Rozibafusp alfa (formerly AMG 570)	Systemic lupus erythematosus
Sotorasib	Advanced colorectal cancer
	Other solid tumors with *KRAS G12C* mutations
Tezepelumab	Chronic obstructive pulmonary disease
AMG 714/PRV-015	Celiac disease
Phase 1 programs	
Efavaleukin alfa (formerly AMG 592)	Inflammatory diseases
AMG 119	Small-cell lung cancer
AMG 133	Obesity
AMG 160	Prostate cancer
AMG 171	Obesity
AMG 176	Hematologic malignancies
AMG 199	Metastatic gastric and gastroesophageal junction cancer
AMG 256	Solid tumors
AMG 330	Acute myeloid leukemia
AMG 397	Hematologic malignancies
AMG 404	Solid tumors
AMG 427	Acute myeloid leukemia
AMG 506	Solid tumors
AMG 509	Prostate cancer
AMG 594[(1)]	Cardiovascular disease
AMG 650	Solid tumors
AMG 673	Acute myeloid leukemia
AMG 701	Multiple myeloma
AMG 757	Small-cell lung cancer
AMG 910	Gastric and gastroesophageal junction cancer

(1) In November 2020, we provided notice to Cytokinetics of termination of our collaboration effective May 20, 2021 and of our intention to transition to them the development and commercialization rights for omecamtiv mecarbil and AMG 594.

Phase 3 Clinical trials investigate the short- and long-term safety and efficacy of our product candidates, compared to commonly used treatments, in a large number of patients who have the disease or condition under study.

Phase 2 Clinical trials investigate side-effect profiles and efficacy of product candidates in a larger patient population than phase 1, but still relatively small, who have the disease or condition under study.

Phase 1 Clinical trials investigate the safety and proper dose ranges of product candidates in a small number of human subjects.

Phase 3 Product Candidate Program Changes

As of February 12, 2020, we had 14 phase 3 programs. As of February 2, 2021, we had 13 phase 3 programs, as regulatory approvals were received for three programs, two programs initiated phase 3 studies, two programs initiated biosimilarity studies, one concluded and one termination and transition of program to Cytokinetics. These changes are set forth in the following table.

Molecule	Disease/condition	Program change
KYPROLIS®	Multiple myeloma	Approved by the FDA
Otezla®	Behçet's disease	Approved by the FDA
	COVID-19	Initiated phase 3 study
RIABNI™	Non-Hodgkin's lymphoma	Approved by the FDA
Sotorasib	NSCLC	Initiated phase 3 study
ABP 654	Psoriasis, psoriatic arthritis and Crohn's disease	Initiated biosimilarity study
ABP 938	Neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy	Initiated biosimilarity study
IMLYGIC®	Metastatic melanoma	Concluded
Omecamtiv mecarbil	Chronic heart failure	Concluded; no longer pursuing our marketing application with the FDA and EC[(1)]

(1) In November 2020, we provided notice to Cytokinetics of termination of our collaboration effective May 20, 2021 and of our intention to transition to them the development and commercialization rights for omecamtiv mecarbil and AMG 594.

Based on our approval pathway that did not require phase 3 study, in January 2021, Nplate® was approved by the FDA for treatment of hematopoietic syndrome of acute radiation syndrome.

Phase 3 Product Candidate Patent Information

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

Molecule	Territory	General subject matter	Estimated expiration*
Sotorasib	U.S.	Compound	2038
Tezepelumab	U.S.	Polypeptides	2029
	Europe	Polypeptides	2028

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

Phases 3 and 2 Program Descriptions

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

EVENITY®

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

IMLYGIC®

IMLYGIC® is an oncolytic immunotherapy derived from herpes simplex virus type 1 (HSV-1). A Phase 3 study evaluating IMLYGIC® in combination with pembrolizumab (KEYTRUDA®) versus pembrolizumab alone for treatment of unresectable stage IIIB to IVM1c melanoma was stopped for futility after an interim analysis by the Data Monitoring Committee. No new safety signals were observed.

KYPROLIS®

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

In August 2020, the FDA approved the expansion of the KYPROLIS® U.S. prescribing information to include its use in combination with DARZALEX® plus dexamethasone in two dosing regimens—once weekly and twice weekly—for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three previous lines of therapy.

Nplate®

Nplate® is a thrombopoietin receptor agonist. It is being investigated in phase 3 studies for chemotherapy-induced thrombocytopenia.

In December, the European Commission approved an expanded indication for use in adult patients who have had immune thrombocytopenia for 12 months or less and who have had an insufficient response to corticosteroids or immunoglobulins.

As noted above, the FDA has approved Nplate® for the treatment of hematopoietic syndrome of acute radiation syndrome.[1]

OLPASIRAN

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

Otezla®

Otezla® is a small molecule that inhibits PDE4. It is being investigated in phase 3 studies for the treatment of patients with mild-to-moderate plaque psoriasis, patients with moderate-to-severe genital psoriasis and, in collaboration with some of the members of the COVID R&D Alliance, adult patients hospitalized with COVID-19.

In May 2020, we announced positive results from the ADVANCE trial, a phase 3, multicenter, randomized, placebo-controlled, double-blind study to assess the efficacy of Otezla® in adults with mild-to-moderate plaque psoriasis. The study showed that oral Otezla® 30 mg twice daily achieved a statistically significant improvement, compared with placebo, in the primary endpoint of the sPGA response at week 16. In addition, the week 16 secondary endpoints of achieving at least 75% improvement from baseline in the percent of affected body surface area (BSA), change in BSA total score from baseline and change in Psoriasis Area and Severity Index (PASI) total score from baseline were each also statistically significant for the treatment effect of Otezla® compared with placebo.

Repatha®

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

In March 2020, we announced positive results from the BEIJERINCK study evaluating the efficacy and safety of Repatha® in patients who are human immunodeficiency virus-positive (HIV+) and have high LDL-C despite stable background lipid-lowering therapy. The study demonstrated that treatment with Repatha® significantly reduced LDL-C.

RIABNI™

RIABNI™, a biosimilar candidate to Rituxan®/MabThera® (rituximab), is an anti-CD20 monoclonal antibody. It is being investigated in a phase 3 study for treatment of rheumatoid arthritis. The reference-product primary conditions are non-Hodgkin's lymphoma, chronic lymphocytic leukemia and rheumatoid arthritis.

[1] Funding and execution of the pivotal study was provided by the National Institute of Allergy and Infectious Diseases (NIAID) and the Priority Review regulatory submission was conducted in partnership with the Biomedical Advanced Research and Development Authority (BARDA).

In December 2020, we announced that the FDA had approved RIABNI™ for the treatment of adult patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, granulomatosis with polyangiitis (Wegener's granulomatosis), and microscopic polyangiitis. RIABNI™ launched in the United States in January 2021.

Rozibafusp alfa

Rozibafusp alfa is a novel bispecific antibody-peptide conjugate that simultaneously blocks the B lymphocyte stimulator (BAFF) and inducible costimulatory ligand (ICOSL) activity. It is being investigated as a treatment for systemic lupus erythematosus.

Sotorasib

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

In December 2020, we announced that the FDA had granted Breakthrough Therapy designation for sotorasib for the treatment of patients with locally advanced or metastatic NSCLC with *KRAS G12C* mutation as determined by an FDA-approved test, following at least one prior systemic therapy. The sotorasib application is being reviewed under the FDA's RTOR pilot program, which aims to explore a more efficient review process that ensures safe and effective treatments are made available to patients as early as possible.

In January 2021, we announced phase 2 results from the CodeBreaK 100 clinical study, evaluating sotorasib in 126 patients with *KRAS G12C-mutant* advanced NSCLC, who had failed a median of two prior lines of anticancer therapies (immunotherapy and/or chemotherapy). Sotorasib demonstrated a confirmed ORR (primary end point) and disease control rate of 37.1% and 80.6%, respectively, a median duration of response of 10 months and median progression-free survival of 6.8 months. Patients were treated with sotorasib 960 mg once daily orally.

Tezepelumab

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

In November 2020, we announced positive results from the registrational phase 3 NAVIGATOR trial, in which the investigational medicine tezepelumab demonstrated a statistically significant reduction in exacerbations compared to placebo in patients with severe asthma. The NAVIGATOR trial met the primary endpoint with tezepelumab added to SoC, demonstrating a statistically significant and clinically meaningful reduction compared to placebo plus SoC in the AAER over 52 weeks in the overall patient population. SoC consisted of medium- or high-dose ICS plus at least one additional controller medication with or without OCS.

In December 2020, we announced that the SOURCE trial had not met the primary endpoint of a statistically significant reduction in the daily OCS dose, without loss of asthma control, with tezepelumab compared to placebo. The results of this trial have no impact on our submission plans.

AMG 714/PRV-015

AMG 714/PRV-015 is a human monoclonal antibody that binds to interleukin-15. It is being investigated for the treatment of celiac disease and is being developed in collaboration with Provention Bio.

ABP 654

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

ABP 938

ABP 938, a biosimilar candidate to EYLEA® (aflibercept), is a vascular endothelial growth factor receptor (VEGFR) Fc fusion protein. It is being investigated in a phase 3 study for neovascular (wet) age-related macular degeneration (AMD). The reference-product primary conditions are wet AMD, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy.

ABP 959

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

Business Relationships

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

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

BeiGene, Ltd.

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

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

Novartis

We are in a collaboration with Novartis to jointly develop and commercialize Aimovig®. In the United States, Amgen and Novartis jointly develop and collaborate on the commercialization of Aimovig®. Amgen, as the principal, recognizes product sales of Aimovig® in the United States, shares U.S. commercialization costs with Novartis and pays Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig®. Novartis pays Amgen double-digit royalties on net sales of the product in the Novartis-exclusive territories and funds a portion of global R&D expenses. In addition, Novartis will make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds are achieved with respect to Aimovig® in the United States. Amgen manufactures and supplies Aimovig® worldwide.

We are currently involved in litigation with Novartis over our collaboration agreements for the development and commercialization of Aimovig®. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Bayer HealthCare LLC

We are in a licensing arrangement with Bayer HealthCare LLC (Bayer) for Nexavar®. In February 2020, we amended the terms of our agreement with Bayer, which transferred all of our operational responsibilities outside the United States to Bayer, including commercial and medical affairs activities. Prior to the amendment of the agreement, we shared equally in the profits outside the United States, excluding Japan. In lieu of this profit share, Bayer now pays us a royalty on sales of Nexavar® at a percentage rate in the low 30s. The rights to develop and market Nexavar® in Japan are reserved to Bayer. In the United States, Bayer pays us a royalty on sales of Nexavar® at a percentage rate in the high 30s.

DaVita Inc.

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

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

Human Capital Resources

Amgen's approach to human capital resource management starts with our mission to serve patients. Our industry exists in a complex regulatory and reimbursement environment. The unique demands of our industry, together with the challenges of running an enterprise focused on the discovery, development, manufacture and commercialization of innovative medicines, require talent that is highly educated and/or has significant industry experience. Additionally, for certain key functions, we require specific scientific expertise to oversee and conduct R&D activities and the complex manufacturing requirements for biopharmaceutical products.

As of December 31, 2020, Amgen had approximately 24,300 staff members, and we have had relatively low global turnover rates. We consider our staff relations to be good; supported by our regular staff engagement assessments, with surveys on a wide range of topics (including engagement in the COVID-19 environment, diversity, inclusion and belonging and ethics). We discuss the results of these surveys with our Board of Directors.

Compensation, Benefits and Development

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

Our base pay program aims to compensate staff members relative to the value of the contributions of their role, which takes into account the skills, knowledge and abilities required to perform each position, as well as the experience brought to the job. We also provide annual incentive programs to reward our staff in alignment with achievement of Company-wide goals that are established annually and designed to drive aspects of our strategic priorities that support and advance our strategy across our Company. The majority of our staff members are also eligible for the grant of equity awards under our long-term incentive program that are designed to align the experience of these staff with that of our shareholders. All staff also participate in a regular performance measurement process that aligns pay to performance and through which staff receive performance and development feedback. To support the development of our staff, we provide a variety of programs, including leadership development programs, virtual instructor-led courses and self-paced learning options.

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

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

Safety and Wellness and Our Response to COVID-19

Creating a safe and healthy workplace for our staff is a priority at Amgen. Our goal is to have a world class safety record through safety leadership, risk management practices and integrating safety throughout our business processes. To foster our safety culture, we implement a comprehensive safety program, driving to understand and mitigate the root cause of safety incidents and manage and control variability. We use leading indicators to assess the effectiveness of our safety programs and make course corrections as needed. Additionally, we perform formal executive management review of functional safety performance for Operations, Global Commercial Operations and R&D on a quarterly basis with a focus on identifying early signals and taking action to drive continuous improvement. Based on our 2019 performance, compared to a benchmark of twelve companies in the pharmaceutical industry, Amgen was in the quartile with the lowest injury rate.

In response to the COVID-19 pandemic and as part of our commitment to work to ensure the safety and well-being of our employees, we have activated our applicable business continuity plans, including having those of our employees who are able to work from home to do so since mid-March 2020. For employees returning to the workplace and the field, we have also taken additional safety measures, including implementing occupancy limits, restricting business travel, providing and requiring the use of personal protective equipment, temperature screening and COVID-19 testing to access our workplaces.

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

Diversity, Inclusion and Belonging

We believe that a diverse and inclusive culture fosters innovation, which supports our ability to serve patients. Further, we also believe our global presence is strengthened by having a workforce that reflects the diversity of the patients we serve. It is with these beliefs in mind that we have continued to strengthen and grow our culture of diversity, inclusion and belonging. Our internal efforts include, in 2019, establishing a Diversity, Inclusion and Belonging Council chaired by our Chief Executive Officer. In 2020, we implemented a global unconscious bias training program, and launched a portal devoted to diversity, inclusion and belonging that includes learning and resources. Further, we are leveraging our Employee Resource Groups (listed below) to represent and support the diversity of Amgen staff:

Employee Resource Groups	
Amgen Asian Association (AAA)	Amgen Black Employee Network (ABEN)
Ability Bettered through Leadership and Education (ABLE), a resource group for the physically or cognitively disabled	
Amgen Early Career Professionals (AECP)	Amgen Indian Subcontinent Network (AISN)
Amgen Latin Employee Network (ALEN)	Amgen LGBTQ and Allies Network (PRIDE)
Amgen Veterans Employees Network (AVEN)	Women Empowered to be Exceptional (WE2)
Women in Information Systems Enrichment (WISE)	

In areas of underrepresentation, we develop plans with a goal of bringing our representation in line with availability, and we also engage in outreach efforts to attract, retain and advance more women and minorities in our workforce. For example, we have worked to enhance our diverse candidate recruiting pool by developing relationships with organizations that can serve as a source of diverse candidates, such as the National Black MBA Association and National Sales Network, as well as historically black colleges and universities. Additionally, at the end of 2020, we became a founding member of OneTen, a coalition of 35 of the world's largest, best-known companies, that aims to hire one million Black Americans (with a specific focus on those without four-year college degrees) into good-paying, family-sustaining jobs over the next ten years. Other examples of actions that we are taking in this area include investment and participation in Healthcare Businesswomen's Association (a global organization focused on development and business networking for women in healthcare) and the University of California, Los Angeles (UCLA) Anderson School of Management women's leadership program.

In an effort to provide additional transparency into the makeup of our workforce, we intend to disclose our 2020 Consolidated EEO-1 Report after our submission of the report to the U.S. Equal Employment Opportunity Commission.

Our Corporate Responsibility and Compliance Committee provides oversight of our policies, programs and initiatives focusing on workforce diversity and inclusion.

Information about Our Executive Officers

The executive officers of the Company as of February 8, 2021, are set forth below.

Mr. Robert A. Bradway, age 58, has served as a director of the Company since 2011 and Chairman of the Board of Directors since 2013. Mr. Bradway has been the Company's President since 2010 and Chief Executive Officer since 2012. From 2010 to 2012, Mr. Bradway served as the Company's President and Chief Operating Officer. Mr. Bradway joined the Company in 2006 as Vice President, Operations Strategy, and served as Executive Vice President and Chief Financial Officer from 2007 to 2010. Prior to joining the Company, Mr. Bradway was a Managing Director at Morgan Stanley in London, where, beginning in 2001, he had responsibility for the firm's banking department and corporate finance activities in Europe. Mr. Bradway has been a director of The Boeing Company, an aerospace company and manufacturer of commercial airplanes, defense, space and securities systems, since 2016. He has served on the board of trustees of the University of Southern California since 2014. From 2011 to 2017, Mr. Bradway was a director of Norfolk Southern Corporation, a transportation company.

Mr. Murdo Gordon, age 54, became Executive Vice President, Global Commercial Operations, in 2018. Prior to joining the Company, Mr. Gordon was Chief Commercial Officer at BMS from 2016 to 2018. Mr. Gordon served as Head of Worldwide Markets at BMS from 2015 to 2016. Prior to this, Mr. Gordon served in a variety of leadership roles at BMS for more than 25 years.

Mr. Jonathan P. Graham, age 60, became Executive Vice President, General Counsel and Secretary in 2019. Mr. Graham joined the Company in 2015. From 2015 to 2019, Mr. Graham was Senior Vice President, General Counsel and Secretary. Prior to joining Amgen, from 2006 to 2015, Mr. Graham was Senior Vice President and General Counsel at Danaher Corporation. From 2004 to 2006, Mr. Graham was Vice President, Litigation and Legal Policy, at General Electric Company (GE). Prior to GE, Mr. Graham was a partner at Williams & Connolly LLP.

Mr. Peter H. Griffith, age 62, became Executive Vice President and Chief Financial Officer in 2020. Mr. Griffith joined the Company in 2019 as Executive Vice President, Finance. Prior to joining Amgen, Mr. Griffith was President of Sherwood Canyon Group, LLC. From 1997 to 2019, Mr. Griffith was a partner at EY and served in a variety of senior leadership roles, with his last position being Global Vice Chair, Corporate Development. Prior to EY, Mr. Griffith was a Managing Director and head of the investment banking division of Wedbush Securities Inc.

Ms. Nancy A. Grygiel, age 53, became Senior Vice President and Chief Compliance Officer in 2020. Ms. Grygiel joined the Company in 2015. From 2016 to 2020, Ms. Grygiel was Vice President, Compliance. Prior to joining Amgen, from 2011 to 2015, Ms. Grygiel served as Vice President, Compliance, Corporate & International, at Allergan, Inc. (Allergan). Prior to Allergan, Ms. Grygiel held several management positions at Mylan Pharmaceuticals, Inc.

Ms. Lori A. Johnston, age 56, became Executive Vice President, Human Resources, in 2019. From 2016 to 2019, Ms. Johnston served as the Company's Senior Vice President, Human Resources. From 2012 to 2016, Ms. Johnston was Executive Vice President and Chief Administrative Officer of Celanese Corporation (Celanese). Prior to Celanese, Ms. Johnston served in a series of progressive leadership roles at Amgen from 2001 to 2012, with her last position being Vice President, Human Resources. Prior to joining the Company, Ms. Johnston held human resources and other positions at Dell Inc.

Mr. David A. Piacquad, age 64, became Senior Vice President, Business Development, in 2014. Mr. Piacquad joined the Company in 2010 and served as Vice President, Strategy and Corporate Development, until his appointment to the role of Vice President, Business Development, in 2014. Prior to joining the Company, from 2009 to 2010, Mr. Piacquad was Principal of David A. Piacquad Consulting LLC. From 2006 to 2009, Mr. Piacquad served as Senior Vice President, Business Development and Licensing, at Schering-Plough Corporation (Schering-Plough). Prior to Schering-Plough, Mr. Piacquad served in a series of leadership roles in finance and business development at J&J, with his last position being Vice President, Ventures and Business Development.

Dr. David M. Reese, age 58, became Executive Vice President, R&D, in 2018. Dr. Reese joined the Company in 2005 and has held leadership roles in development, medical sciences and discovery research. Dr. Reese was Senior Vice President, Translational Sciences and Oncology, from 2017 to 2018 and Senior Vice President, Translational Sciences, from 2015 to 2017. Prior to joining Amgen, Dr. Reese was director of Clinical Research at the Breast Cancer International Research Group from 2001 to 2003 and a cofounder, president and chief medical officer of Translational Oncology Research International, a not-for-profit academic clinical research organization, from 2003 to 2005. Dr. Reese previously served on the faculty at UCLA and the University of California, San Francisco.

Mr. Esteban Santos, age 53, became Executive Vice President, Operations, in 2016. Mr. Santos joined the Company in 2007 as Executive Director, Manufacturing Technologies. From 2008 to 2013, Mr. Santos held a number of Vice President roles at the Company in engineering, manufacturing, site operations and drug product. From 2013 to 2016, Mr. Santos was Senior Vice President, Manufacturing. Prior to joining the Company, Mr. Santos served as Site General Manager of J&J's Cordis operation in Puerto Rico. Prior to J&J, Mr. Santos held several management positions in GE's industrial and transportation businesses.

Geographic Area Financial Information

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

Investor Information

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

Item 1A. RISK FACTORS

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

SUMMARY

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

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

Risks Related to Government Regulations and Third-Party Policies

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

Risks Related to Competition

- Our products face substantial competition and our product candidates are also likely to face substantial competition.
- Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.
- We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.
- Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively affect our business.

Risks Related to Research and Development

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

Risks Related to Operations

- We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.
- We rely on third-party suppliers for certain of our raw materials, medical devices and components.
- Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

General Risk Factors

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

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

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

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

Our clinical trials have been, and are expected to continue to be, adversely affected by the COVID-19 pandemic. We have clinical work ongoing at investigational sites across the globe. A number of clinical trial sites, including those in regions experiencing new or resurgent outbreaks of COVID-19, have restricted site visits and imposed restrictions on the initiation of new clinical trials and/or patient visits to protect both site staff and patients from possible COVID-19 exposure that has stopped or slowed clinical trial activities. In response to the safety concerns related to COVID-19, we have suspended, and will continue to suspend, enrollment and screening in clinical trials where sites are unable to perform clinical trial work due to COVID-19 or there is uncertainty around the ability of sites to ensure subject safety or data integrity. Further, the COVID-19 pandemic has adversely affected, and may continue to adversely affect, our ability to enroll or to continue to enroll certain required post-marketing studies, including pediatric studies. While many of our clinical trial activities have recommenced over the course of 2020, the initial disruption caused by the COVID-19 pandemic to our clinical trials and our clinical trial plans and timelines, and any similar future disruptions (including as a result of the current surge and lockdowns in numerous regions), may have a significant adverse effect on our product development and launches, and, in turn, on future product sales, business and results of operations. For example, to ensure patient safety we initially paused enrollment of our sotorasib Phase 1 combination cohort with Keytruda® and Phase 3 lung cancer study, and such interruptions in enrollment may ultimately affect the timeline of these or other studies. Additionally, while we are investing in research, collaborations and operational support to potentially develop and/or produce treatments for COVID-19, such activities may not result in therapeutic candidates, product approvals, successful production and/or significant commercial value being derived from potential COVID-19-related medicines.

As a result of the COVID-19 pandemic, we have experienced, and expect to continue to experience, regulatory delays, including delays in receiving regulatory advice, reviews of applications, or performance of inspections required for approvals. The pandemic may also result in greater regulatory uncertainty. For example, the FDA and the EMA have issued guidance to provide biopharmaceutical manufacturers greater flexibility in certain regulatory areas, including protocol deviations and adverse event reporting. However, such flexibility may result in greater uncertainty regarding the expectations of such health authorities in relation to this guidance. Additionally, there may be delays in ongoing or new patent office or patent proceedings in the United States or internationally that may delay the outcome of such proceedings. Such delays and disruptions could have a significant adverse effect on our product development and launches, product sales, business and results of operations.

In response to COVID-19, we have activated our applicable business continuity plans, including suspending U.S. in-person meetings and interactions with the healthcare community and professionals in a substantial number of states, suspending, as a general matter, all international business travel and the majority of domestic travel within the United States, and U.S. employees who are able to work from home have been doing so since mid-March 2020. Our ability to perform critical functions and maintain operations have been adversely affected and could continue to be adversely affected as a result of such workforce restrictions, and the COVID-19-related support programs we have put into place for our staff, suppliers and customers have increased, and are expected to continue to increase, our operating expenses and reduce the efficiency of our operations. Notwithstanding such support programs, the COVID-19 pandemic's effects on the health and availability of our workforce, as well as those of the third parties on which we rely, could have an adverse effect on our business. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to COVID-19, we may not be able to execute on our business strategy and our operations may be adversely affected. Additionally, disruptions in public and private infrastructure, including transportation and supply chains, have adversely affected, and continue to adversely affect, the efficiency of our business operations. Also, the transition of the majority of our workforce to a remote work environment in response to COVID-19, as well as that of our third-party service providers, have exacerbated certain risks to our business, including, but not limited to, those associated with an increased demand for information technology resources, increased risk of cybersecurity attacks (including social engineering attacks), and increased risk of unauthorized dissemination of sensitive personal information or our proprietary or confidential information. As the pandemic continues to progress, we have observed an increase in cybersecurity incidents, predominantly ransomware and social engineering attacks, experienced by our third-party service providers. Further, government entities have also been the subject of cyberattacks. The EMA disclosed in December 2020 that it had been the subject of a cyberattack that targeted and accessed third-party documents relating to regulatory submissions, and that such documents were published on the internet (some of which were manipulated prior to publication). Such third-party and governmental incidents have created the risk of the loss of availability and/or control of information (including information related to our clinical trials) important to the operation of our business. See *A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.* In the future, as the pandemic progresses and afterwards, we may experience significant adverse effects on our commercial and clinical manufacturing activities, our operations, and our cybersecurity, and our suppliers and vendors may also experience significant disruptions to their activities and operations on which we depend, as a result of these cybersecurity incidents.

Federal, state and local, and international governmental policies and initiatives designed to reduce the transmission of COVID-19 also have resulted in the cancellation or delay of diagnostic, elective, specialty and other procedures and appointments to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19. These measures and challenges will likely continue to varying degrees for the duration of the pandemic and have significantly reduced patient access to, and administration of, certain of our drugs. For example, Prolia® is a product requiring administration by a healthcare provider in doctors' offices or other healthcare settings that are affected by COVID-19. The U.S. label for Prolia® instructs healthcare professionals who discontinue Prolia® to transition the patient to an alternative antiresorptive, including oral treatments that do not require administration by a healthcare provider. Further, as a result of COVID-19, oncology patients, in consultation with their doctors, may be selecting less immunosuppressive therapies or therapies that do not require administration in a hospital setting, potentially adversely affecting certain of our products. Also, new patients are less likely to be diagnosed and/or to start therapeutics during the pandemic. Once the pandemic subsides, we anticipate there will be a substantial backlog of patients seeking appointments with physicians relating to a variety of medical conditions, and as a result, patients seeking treatment with certain of our products may have to navigate limited provider capacity, and this limited provider capacity could have a continued adverse effect on our sales following the opening up of various geographies and/or the end of the pandemic. Further, the effects of the COVID-19 pandemic may result in long-term shifts in preferences among healthcare professionals and patients toward treatments that do not require administration by healthcare professionals or visits to medical facilities.

The legislative and regulatory environment governing our businesses is dynamic and changing frequently in response to COVID-19. For example, the COVID-19 pandemic has resulted in increased interest in compulsory licenses, march-in rights or other governmental interventions, both in the United States and internationally, related to the procurement of drugs, such as the WHO's COVID-19 Technology Access Pool initiative, which provides an approach for sharing all intellectual property, information and clinical trial data necessary to enable generic drug manufacturing. *See Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation*. Further, the challenges of the pandemic have resulted in the exploration of signification legislation to address the need to supply medicines to address COVID-19. Pursuant to the declaration of a national emergency in the United States in March 2020 under the Stafford Act, state and local governments may request access to discounted pricing for certain items related to the COVID-19 response. The Coronavirus Aid, Relief and Economic Security (CARES) Act implements initiatives to provide advanced payments from Medicare to healthcare providers, clinics and physicians and to require Medicare plans to provide up to a 90-day supply of Part D drugs. However, despite such initiatives and government support, there may be adverse effects on the timing and collectability of our customer receivables as a result of the COVID-19 pandemic. See *Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively affect our business.* The COVID-19 pandemic has also resulted in a significant increase in unemployment and underemployment which may continue after the pandemic. Such a significant increase in unemployment or other disruptions in the labor market have led to a substantial reduction in disposable income and, in the U.S., access to healthcare insurance, including reductions in the commercially insured population that has led to growth (and is expected to continue to lead to growth) in Medicaid enrollment, which has adversely affected our product sales. See *Global economic conditions may negatively affect us and may magnify certain risks that affect our business*. Such reduction in healthcare insurance could be compounded by any full or partial repeal of the ACA by the U.S. Supreme Court. Further, globally, the substantial pressures placed on governmental and payor budgets as a result of the COVID-19 pandemic and the projected governmental budget shortfalls caused by significantly reduced economic activity during and potentially after the COVID-19 pandemic, together with the long-term impact from the pressures on healthcare systems, may result in greater and continued downward price pressure on biopharmaceutical products and increased intensity of stakeholder negotiations across the biopharmaceutical value chain. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability*.

As the pandemic continues, and if conditions worsen or if the duration of the pandemic extends significantly, we expect to experience additional adverse effects on our operational and commercial activities, customer purchases and our collections of accounts receivable. It is unclear which adverse effects may be material, and it remains uncertain the degree to which these adverse effects would impact our future operational and commercial activities, customer purchases and our collections even if conditions begin to improve. There was a resurgence in COVID-19 infections in numerous jurisdictions in the autumn of 2020 and winter of 2020-2021, resulting in the reinstatement of stricter restrictions and shutdowns in a number of jurisdictions. It is expected that the pandemic will continue to ebb and flow, with different jurisdictions having higher levels of infections than others over the course of the pandemic. In addition to existing travel restrictions, jurisdictions may continue or reinstate border closures, impose or reimpose prolonged quarantines and further restrict travel and business activity, which could significantly affect our ability to support our operations and customers and the ability of our employees to get to their workplaces to discover, study, develop and produce our product candidates and products, disrupt the movement of our products through the supply chain, and prevent or discourage patients from seeking healthcare services and the administration of certain of our products. Further, in connection with the global outbreak and spread of COVID-19 and in an effort to increase the wider availability of needed medical products, we or our suppliers may elect to, or governments may require us or our suppliers to, allocate manufacturing capacity (for example pursuant to the U.S. Defense Production Act) in a way that adversely affects our regular operations, customer relationships and financial results. In the U.S., on January 21, 2021, President Biden issued an Executive Order instructing federal agencies to use all available legal authorities, including the Defense Production Act, to improve current and future pandemic response and biological threat preparedness. The rapid reallocation of resources for the treatment and prevention of COVID-19, including the production of COVID-19 vaccinations or related therapies, such as our agreement to contribute to the production of one of Lilly's potential COVID-19 antibody therapies, could also result in increased competition for, or reduced availability of, materials used in the manufacturing or distribution of our products. In addition, unpredictable increases in demand for certain of our products could exceed our capacity to meet such demand, which could adversely affect our financial results and customer relationships.

The COVID-19 pandemic and the volatile global economic conditions stemming from it may precipitate or amplify the other risks described in this "Risk Factors" section, which could materially adversely affect our business, operations and financial conditions and results. For example, if a natural disaster or other potentially disruptive event occurs concurrently with the COVID-19 pandemic, such disaster or event could deplete our inventory levels and we could experience a disruption to our manufacturing or ability to supply our products. Further, the global pandemic has exacerbated geopolitical tensions, and some countries, such as China, may be especially vulnerable to such dynamics. If relations between the United States and China or other governments deteriorates, our business and investments in China or other such markets may also be adversely affected. See *Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.*

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

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

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

Our information technology systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. Further, as the majority of our employees are working remotely, our reliance on our and third-party information technology systems has increased substantially and is expected to continue to increase. The complexity and interconnected nature of our systems makes them potentially vulnerable to breakdown or other service interruptions. Our systems are also subject to frequent cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity and are becoming increasingly difficult to detect. Such attacks could include the use of harmful and virulent malware, including ransomware or other denials of service, that can be deployed through various means, including the software supply chain, e-mail, malicious websites and/or the use of social engineering. Attacks such as those experienced by governmental entities (including those that approve and/or regulate our products, such as the EMA) and other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access or protect important data, and could have a material adverse effect on our ability to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and/or distributing our products. For example, in 2017, a pharmaceutical company experienced a cyberattack involving virulent malware that significantly disrupted its operations, including its research and sales operations and the production of some of its medicines and vaccines. As a result of the cyberattack, its orders and sales for certain products in certain markets were negatively affected. In December 2020, SolarWinds Corporation, a leading provider of software for monitoring and managing information technology infrastructure, disclosed that it had suffered a cybersecurity incident whereby attackers had inserted malicious code into legitimate software updates for its products that were installed by myriad private and government customers, enabling the attackers to access a backdoor to such systems. See *The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations* for a discussion of the cyberattack on the EMA.

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

Domestic and global government regulators, our business partners, suppliers with whom we do business, companies that provide us or our partners with business services and companies we may acquire may face similar risks, and security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. For example, in 2019, two vendors that perform testing and analytical services that we use in developing and manufacturing our products have experienced cyberattacks, and in April and September of 2020, vendors that provide us with information technology services and clinical data services, respectively, each experienced ransomware attacks. Each of these incidents required us to disconnect our systems from those vendors' systems. While we were able to reconnect our systems following restoration of these vendor's capabilities without significantly affecting product availability, a more extended service outage affecting these or other vendors, particularly where such vendor is the single source from which we obtain the services, could have a material adverse effect on our business or results of operations. In addition, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers and patients.

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

We are also subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and developing and the subject of significant attention globally. For example, we are subject to the EU's GDPR, which became effective in May 2018, and the California Consumer Privacy Act of 2018, which became effective in January 2020, both of which provide for substantial penalties for non-compliance. Other jurisdictions where we operate have enacted or proposed similar legislation and/or regulations. Failure to comply with these current and future laws could result in significant penalties and could have a material adverse effect on our business and results of operations.

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

As we continue our expansion efforts in emerging markets around the world, through acquisitions and licensing transactions as well as through the development and introduction, both independently and through collaborations such as our collaboration with BeiGene, of our products in new markets, we face numerous risks to our business. There is no guarantee that our efforts and strategies to expand sales in emerging markets will succeed. Our international business, including in China and emerging market countries, may be especially vulnerable to periods of global and local political, legal, regulatory and financial instability, including issues of geopolitical relations, the imposition of international sanctions in response to certain state actions and/or sovereign debt issues. We may also be required to increase our reliance on third-party agents and unfamiliar operations and arrangements including those previously utilized by companies we partner with or acquire in emerging markets. See *We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.* Our expansion efforts in China and emerging markets around the world is dependent upon the establishment of an environment that is predictable, navigable and supportive of biopharmaceutical innovation, sustained access for our products and limited pricing controls. For example, China continues to strengthen regulations on the collection, use and transmission of Chinese human genetic resources, and has expanded regulations on the conduct of biotechnology R&D activities in China. Our applications to the Human Genetic Resources Administration of China (HGRAC) seeking approval to conduct clinical trials in China are delayed pending further guidance from HGRAC. Our international operations and business may also be subject to less protective intellectual property or other applicable laws, diverse data privacy and protection requirements, changing tax laws and tariffs, trade restrictions or other barriers designed to protect industry in the home country against foreign competition, far-reaching antibribery and anticorruption laws and regulations and/or evolving legal and regulatory environments.

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

RISKS RELATED TO GOVERNMENT REGULATIONS AND THIRD-PARTY POLICIES

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

Sales of our products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers continue to pursue initiatives to manage drug utilization and contain costs. These payers are increasingly focused on the effectiveness, benefits and costs of similar treatments, which could result in lower reimbursement rates for our products or narrower populations for whom payers will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payer dynamics, have limited, and are likely to continue to limit, our ability to set or adjust the price of our products based on their value, which could have a material adverse effect on our business. In the United States, particularly over the past few years, a number of legislative and regulatory proposals have been introduced in an attempt to lower drug prices. These include proposals that would allow the U.S. government to negotiate drug price directly, limit drug reimbursement based on prices abroad or permit importation of drugs from Canada. Proposals focused on drug pricing are likely to continue to be proposed and may be adopted and implemented in some form.

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

A substantial portion of our U.S. business relies on reimbursement from federal government healthcare programs and commercial insurance plans regulated by federal and state governments. See Item 1. Business—Reimbursement. Our business has been and will continue to be affected by legislative actions changing U.S. federal reimbursement policy. Since late 2018, Congressional focus on drug pricing has increased, placing our industry under greater Congressional scrutiny. For example, in early 2019, the chair of the House Oversight and Reform Committee sent letters to twelve different biopharmaceutical manufacturers, including Amgen, seeking documents and detailed information about such companies' drug pricing practices. Subsequently, in the fall of 2020, the House Oversight and Reform Committee released staff reports and held hearings with executives from six biopharmaceutical manufacturers, including Amgen, about their companies' drug pricing practices. Also, between 2019 and 2020, a number of other Congressional committees held hearings and evaluated proposed legislation on drug-pricing and payment policy. For example, in 2019, the Senate Finance Committee advanced a bill that would, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and/or D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries, and require higher/additional manufacturer discounts in Medicare Part D. Additionally, in late 2019, a drug-pricing bill, H.R. 3, passed the House of Representatives, which would, among other things, enable direct price negotiations by the federal government on certain drugs (with the maximum price paid by Medicare capped by prices derived from an international index), includes a penalty for failing to reach agreement with the government, and requires that manufacturers offer these negotiated prices to other payers. We expect H.R. 3, or some similar proposed legislation, to be debated by Congress this year. Additional legislative or regulatory proposals have been introduced by members of Congress and the prior Administration that, if enacted and implemented in whole or in part, could also affect access to and sales of our products, including, but not limited to, proposals to allow importation of prescription medications from Canada or other countries and to set Medicare payment rates using international price referencing. Further, in mid-2020, the prior Administration announced a number of Executive Orders intended to reduce the cost of biopharmaceuticals for patients, including a MFN policy for Medicare Parts B and D, under which the HHS was directed to take steps to implement payment models that set Medicare purchase prices based on the lowest price available in economically comparable countries for certain Part B and Part D medicines. In September 2020, in response to the corresponding Executive Order, HHS released a final rule to allow states (or other nonfederal government entities) to submit proposals to the FDA allowing for the importation of certain nonbiologic prescription drugs from Canada. Currently, the rule is being challenged by litigation, however, should such litigation be unsuccessful and should the Secretary of HHS authorize state proposals for importation, this rule could allow the importation of Canadian versions of certain of Amgen's products (including Otezla®), that could have a material adverse effect on Amgen's business. Further, in November 2020, also in response to the corresponding Executive Order, HHS released an interim final rule to implement the MFN pricing approach. If implemented, the MFN rule would set the reimbursement rate for 50 Medicare Part B drugs (including our products, such as Prolia®, XGEVA®, KYPROLIS®, Neulasta®, Nplate®, EPOGEN® and Aranesp®) equal to the lowest adjusted price for such products of the 22 Organization for Economic Co-operation and Development (OECD) nations. Lawsuits have been filed by certain trade groups challenging the implementation of this MFN rule based on, among other things, procedural defects. Late in 2020, in the case filed by the Biotechnology Industry Organization and others, the U.S. District Court for the Northern District of California issued a preliminary injunction preventing the rule from taking effect nationwide, pending the government's completion of required administrative procedures. The case was subsequently stayed by the court and the parties were ordered to file a joint status report by April 23, 2021. Another case, filed by the Pharmaceutical Research and Manufacturers of America and others in the U.S. District Court for the District of Maryland, was also stayed. Notwithstanding these stays, the MFN rule's approach to drug pricing and other similar approaches, remain of interest. Further, despite the change in Administration, we expect continued significant focus on healthcare and similar drug pricing proposals, including proposals similar to the MFN rule, for the foreseeable future.

Our business has been, and is expected to continue to be, affected by changes in U.S. federal reimbursement policy resulting from federal regulations and federal demonstration projects. For example, the previous Administration released a drug pricing blueprint in 2018 which introduced an array of policy ideas intended to increase competition, improve the negotiating power of the federal government, reduce drug prices and lower patient out-of-pocket costs with the potential to significantly affect, whether individually or collectively, our industry. Such policy ideas included, but were not limited to, moving coverage and reimbursement for Medicare Part B drugs into Medicare Part D and instituting a competitive acquisition program for Part B drugs in which competing third-party vendors take on the financial risk of acquiring drugs and billing Medicare.

Also, over the past three years, federal agencies, including the Centers for Medicare & Medicaid Services (CMS), announced a number of recommendations, policies, proposals and demonstration projects to implement various elements of the drug pricing blueprint. CMS is the federal agency responsible for administering Medicare and overseeing state Medicaid programs and Health Insurance Marketplaces and has substantial power to implement policy changes or demonstration projects that can quickly and significantly affect how drugs, including our products, are covered and reimbursed. CMS issued guidance to allow certain Medicare plans offered by private insurance companies to require that patients receiving Medicare Part B drugs first try a drug preferred by the plan before covering another therapy (Step Therapy) and lowered reimbursement rates for new Medicare Part B drugs. Further, HHS issued a final rule under Medicare Part D revising the regulations under the federal antikickback statute to encourage PBMs to use rebates received from biopharmaceutical manufacturers to reduce patient cost-sharing at the point of sale. Changes to the regulations will be phased-in beginning on March 22, 2021, with all changes effective as of January 1, 2023. However, there are numerous logistical hurdles to overcome before such rule can be effectively implemented and it is unclear how PBMs will change their business practices in response. Furthermore, a trade association representing PBMs recently filed litigation challenging this HHS final rule. Given these uncertainties, it remains unclear when any anticipated benefits to patients will materialize. The incoming Administration also could develop and seek to advance a range of policy proposals that could impact U.S. federal reimbursement policy for drugs and biologics.

CMS policy changes and demonstration projects to test new care, delivery and payment models can significantly affect how drugs, including our products, are covered and reimbursed. In end-stage renal disease (ESRD), CMS uses bundled payment rates. Between 2018 and 2020, Sensipar® and Parsabiv®, our calcimimetics that are used in dialysis clinics, were eligible for temporary drug add-on payment adjustments (TDAPA) to the bundled rate. In November 2020, CMS released its final rule ending the TDAPA for calcimimetics and adjusting ESRD Prospective Payment System bundled rates on January 1, 2021 by $9.93 per dialysis treatment for calcimimetics, and we expect the sales of our calcimimetics to be materially adversely affected by this rule change. Additionally, CMS created a new mandatory payment model effective January 1, 2021 focused on encouraging greater use of home dialysis and kidney transplants for ESRD patients that could result in changes to treatment of dialysis patients, including reduction of the use of our ESAs. Further, back in November 2019, CMS announced additional voluntary payment models for nephrologists and dialysis facility partners that also seek to encourage home dialysis and preemptive transplantation through increased risk sharing, but due to COVID-19, the start date of such programs has been pushed back to April 1, 2021. CMS has also solicited suggestions regarding other potential care models. In 2016, CMS initiated the Oncology Care Model demonstration, which provides participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare costs without negatively affecting the efficacy of care, that has been extended by one year (to 2022) due to COVID-19. We believe the Oncology Care Model has reduced utilization of certain of our oncology products by participating physician practices and expect it to continue to do so in the future. Additionally, in late 2019, CMS announced a request for information on the Oncology Care First model, a new voluntary model that builds on the Oncology Care Model. CMS recently finalized a rule that, starting January 1, 2023, unless a manufacturer can ensure that the full amount of manufacturer patient assistance programs is passed on to the patient, such amount will be treated as a price reduction that will be taken into account when reporting our Best Price and/or Average Manufacturer Price (AMP). Given the use by PBMs and insurers of copay accumulator adjustment programs to apply such patient assistance for the benefit of such companies and not to defray costs to patients, it could be difficult to impossible for manufacturers to ensure that the full value of such amounts is being passed on to the patient. This new policy, if implemented, would have significant implications for our ability to offer copay assistance programs.

In this dynamic environment, we are unable to predict which or how many federal policy, legislative, regulatory, executive or administrative changes may ultimately be, or effectively estimate the consequences to our business if, enacted and implemented. However, to the extent that these or other federal government initiatives further decrease or modify the coverage or reimbursement available for our products, require that we pay increased rebates or shift other costs to us, limit or affect our decisions regarding the pricing of or otherwise reduce the use of our U.S. products, or limit our ability to offer co-pay payment assistance to commercial patients, such actions could have a material adverse effect on our business and results of operations.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products. U.S. government price reporting regulations are complex and may require a biopharmaceutical manufacturer to update certain previously submitted data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data, we also may be required to pay additional rebates and provide additional discounts.

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

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

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

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

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

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

Outside the United States, we expect countries will also continue to take actions to reduce their drug expenditures. See Item 1. Business—Reimbursement. IRP has been widely used by many countries outside the United States to control costs based on an external benchmark of a product's price in other countries. IRP policies can change quickly and frequently and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. In addition, countries may refuse to reimburse or may restrict the reimbursed population for a product when their national health technology assessments do not consider a medicine to demonstrate sufficient clinical benefit beyond existing therapies or to meet certain cost effectiveness thresholds. For example, despite the EMA's approval of Repatha® for the treatment of patients with established atherosclerotic disease, the reimbursement for Repatha® in France is limited to a narrower patient population (such as those with homozygous familial hypercholesterolemia) following a national health technology assessment. While the pricing and reimbursement process in that country remains ongoing, the assessment currently limits our efforts in France to expand Repatha® access to the broader patient population covered by the approved label. Some countries decide on reimbursement between potentially competing products through national or regional tenders that often result in one product receiving most or all of the sales in that country or region. Failure to obtain coverage and reimbursement for our products, a deterioration in their existing coverage and reimbursement, or a decline in the timeliness or certainty of payment by payers to physicians and other providers has negatively affected, and may further negatively affect, the ability or willingness of healthcare providers to prescribe our products for their patients and otherwise negatively affect the use of our products or the prices we realize for them. Such changes have had, and could in the future have, a material adverse effect on our product sales, business and results of operations.

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

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

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

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

Our tax returns are routinely examined by tax authorities in the United States and other jurisdictions in which we do business, and a number of audits are currently underway. Tax authorities, including the Internal Revenue Service (IRS), are becoming more aggressive in their audits and are particularly focused on the allocations of income and expense among tax jurisdictions. In 2017, we received a Revenue Agent Report (RAR) and a modified RAR from the IRS for the years 2010, 2011 and 2012 proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. However, we have been unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a Notice of Deficiency which we would expect to vigorously contest through the judicial process. In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagree with the 2013, 2014 and 2015 proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. The IRS audit for years 2016, 2017 and 2018 is expected to start in the near term. We are also currently under examination by a number of other state and foreign tax jurisdictions.

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

Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities and changes in applicable tax laws, regulations or administrative interpretations thereof. The Tax Cuts and Jobs Act (the 2017 Tax Act) is complex and a large volume of regulations and guidance has been issued and could be subject to different interpretations. We could face audit challenges to our application of the 2017 Tax Act. The new Administration and Congress could make changes to existing tax law, including an increase in the corporate tax rate and the tax rate on foreign earnings. Changes to existing tax law in the U.S., the U.S. territory of Puerto Rico, or other jurisdictions, including efforts by the OECD to align countries on corporate tax matters that would likely result in tax increases where we do business could have a material adverse effect on the results of our operations.

Our business may be affected by litigation and government investigations.

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

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

RISKS RELATED TO COMPETITION

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

We operate in a highly competitive environment. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We expect that our products and product candidates will compete with existing drugs, new drugs currently in development, drugs currently approved for other indications that may later be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. Large pharmaceutical companies and generics manufacturers of pharmaceutical products are expanding into the biotechnology field, and some pharmaceutical companies and generics manufacturers have formed partnerships to pursue biosimilars. With the proliferation of companies pursuing biopharmaceuticals, a number of our product candidates may enter markets with one or more competitors or with competitors soon to arrive. In addition, some of our competitors may have technical, competitive or other advantages over us for the development of technologies and processes or greater experience in particular therapeutic areas, and consolidation among pharmaceutical and biotechnology companies can enhance such advantages. These advantages may make it difficult for us to compete with them successfully to discover, develop and market new products and for our current products to compete with new products or new product indications they may bring to market. As a result, our products have been competing and may continue to compete, and our product candidates may compete, against products or product candidates that offer higher rebates or discounts, lower prices, equivalent or superior efficacy, better safety profiles, easier administration, earlier market availability or other competitive features. If we are unable to compete effectively, this could reduce sales, which could have a material adverse effect on our business and results of operations.

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

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. Driven by cost pressures, efforts to limit or weaken patent protection for our industry are increasing. For example, the COVID-19 pandemic has resulted in increased interest in compulsory licenses, march-in rights or other governmental interventions, both in the United States and internationally, related to the procurement of drugs. See *The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations.* Third parties have challenged and may continue to challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. Challenges to patents may come from potential competitors or from parties other than those who seek to market a potentially-infringing product. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We have been in the past, are currently and expect to be in the future, involved in patent litigation. These matters have included, and may in the future include, litigation with manufacturers of products that purport to be biosimilars of certain of our products for patent infringement and for failure to comply with certain provisions of the Biologics Price Competition and Innovation Act of 2009 (BPCIA). A determination made by a court, agency or tribunal concerning infringement, validity, enforceability, injunctive or economic remedy, or the right to patent protection, for example, are typically subject to appellate or administrative review. Upon review, such initial determinations may be afforded little or no deference by the reviewing tribunal and may be affirmed, reversed or made the subject of reconsideration through further proceedings. A patent dispute or litigation has not discouraged, and may not in the future discourage, a potential violator from bringing the allegedly-infringing product to market prior to a final resolution of the dispute or litigation. The period from inception until resolution of a patent dispute or litigation is subject to the availability and schedule of the court, agency or tribunal before which the dispute or litigation is pending. We have been, and may in the future be, subject to competition during this period and may not be able to recover fully from the losses, damages and harms we incur from infringement by the competitor product even if we prevail. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities, be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Further, under the Hatch-Waxman Act, our products approved by the FDA under the FDCA have been, and may in the future be, the subject of patent litigation with generics competitors before expiry of the five-year period of data exclusivity provided for under the Hatch-Waxman Act and prior to the expiration of the patents listed for the product. Likewise, our innovative biologic products have been, and may in the future be, the subject of patent litigation prior to the expiration of our patents and, with respect to competitors seeking approval as a biosimilar or interchangeable version of our products, prior to the 12-year exclusivity period provided under the BPCIA. In addition, we may face patent litigation involving claims that the biosimilar product candidates we are working to develop infringe the patents of other companies, including those that manufacture, market or sell the applicable reference products or who are developing or have developed other biosimilar versions of such products. Due to the COVID-19 pandemic, there may be delays in ongoing or new patent office or court proceedings in the U.S. or abroad that may delay the outcome of such proceedings. While we have attempted, and expect to continue to attempt, to challenge the patents held by other companies, our efforts may be unsuccessful. Alternatively, such patents have contributed, and may in the future contribute, to a decision by us to not pursue all of the same labeled indications as are held by these companies. For examples of and information related to our patent litigation, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

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

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

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

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

In the United States, the BPCIA authorizes the FDA to approve biosimilars via a separate, abbreviated pathway. See Item 1. Business—Government Regulation—Regulation in the United States—Approval of Biosimilars. The first biosimilar entrant into the U.S. market was Sandoz's Zarxio® (filgrastim-sndz), a biosimilar version of NEUPOGEN®, in 2015. Since then, the FDA has approved additional biosimilars, including biosimilar versions of Neulasta®, EPOGEN® and ENBREL, and a growing number of companies have announced that they are also developing biosimilar versions of our products. Four biosimilar versions of Neulasta® are now marketed in the United States, and we expect other biosimilar versions of Neulasta® to receive approval in 2021 and beyond. Impact to our Neulasta® sales has accelerated as additional competitors have launched. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. An approved biosimilar version of EPOGEN® has also launched in the United States, and we are currently involved in patent litigations with the manufacturers of the approved biosimilar versions of ENBREL. Manufacturers of biosimilars have attempted, and may in the future attempt, to compete with our products by offering lower list prices, greater discounts or rebates, or contracts that offer longer-term pricing or a broader portfolio of other products. Companies pursuing development of biosimilar versions of our products have challenged and may continue to challenge our patents well in advance of the expiration of our material patents. For example, we recently successfully defended our ENBREL patents against a litigation challenge. For examples of and information related to our biosimilars and generics patent litigation, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. See *Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.*

The U.S. pathway includes the option for biosimilar products that meet certain criteria to be approved as interchangeable with their reference products. Some companies currently developing or already marketing biosimilars may seek to obtain interchangeable status from the FDA, which could potentially allow pharmacists to substitute those biosimilars for our reference products without prior approval from the prescriber in most states. In November 2019, the FDA issued draft guidance that provides that comparative immunogenicity studies will not generally be expected for biosimilar and interchangeable insulin products. This may open the door for other product-specific guidance development and the removal of the expectation for certain studies, which may contribute to increased biosimilar competition for our innovative products.

In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law's provisions regarding which new products receive data exclusivity. In late 2019, the previous Administration agreed to remove from the United States-Mexico-Canada Agreement a requirement for at least 10 years of data exclusivity for biologic products. Also, the FDA is considering whether subsequent changes to a licensed biologic would be protected by the remainder of the reference product's original 12-year exclusivity period (a concept known in the generic drug context as "umbrella exclusivity"). If the FDA were to decide that umbrella exclusivity does not apply to biological reference products or were to make other changes to the exclusivity period, this could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, legislative and regulatory efforts to promote competition through policies enabling easier generic and biosimilar approval and commercialization, including efforts to lower standards for demonstrating biosimilarity or interchangeability, limit patents that may be litigated and/or patent settlements, implement preferential reimbursement policies for biosimilars and passage of new laws requiring more disclosure in the FDA's Orange and Purple Books.

Upon the expiration or loss of patent protection and/or applicable exclusivity for one of our small molecule products, we can lose the majority of revenues for that product in a very short period of time. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. Additionally, if one of our small molecule products is the subject of an FDA Written Request for pediatric studies and we are unable to adequately complete these studies, we may not obtain the pediatric exclusivity award that extends existing patents for the product by an additional six months. For example, as a result of the product already introduced and/or that could further be introduced into the U.S. market, our product sales for Sensipar® have been adversely affected and could be further materially and adversely affected by competing generics.

California is the first state to have passed legislation, effective on January 1, 2020, against "pay for delay" settlements of patent infringement claims filed by manufacturers of generics or biosimilars where anything of value is given in exchange for settlement. Under this law, such settlement agreements are presumptively anticompetitive. The law may result in prolonged litigation and fewer settlements. Other states, including Connecticut, New York, Illinois, and Minnesota, may adopt similar laws or a similar law could be adopted at the federal level.

While we are unable to predict the precise effects of biosimilars and generics on our products, we are currently facing and expect to face greater competition in the United States, Europe and elsewhere in 2021 and beyond as a result of biosimilar and generic competition and, in turn, downward pressure on our product prices and sales. This competition has had and could increasingly have a material adverse effect on our product sales, business and results of operations.

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

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

RISKS RELATED TO RESEARCH AND DEVELOPMENT

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

Amgen invests heavily in R&D. Successful product development in the biotechnology industry is highly uncertain, and very few R&D projects produce commercial products. Product candidates, including biosimilar product candidates, or new indications for existing products (collectively, product candidates) that appear promising in the early phases of development may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it achieved its primary endpoints and/or demonstrated positive preclinical or early clinical trial results, for reasons that could include changes in the standard of care of medicine or expectations of health authorities;
- the product candidate was not effective or not more effective than currently available therapies in treating a specified condition or illness;
- the product candidate was not cost effective in light of existing therapeutics;
- the product candidate had harmful side effects in animals or humans;

- the necessary regulatory bodies, such as the FDA or EMA, did not approve the product candidate for an intended use;
- the product candidate was not economical for us to manufacture and commercialize;
- other parties had or may have had proprietary rights relating to our product candidate, such as patent rights, and did not let us sell it on reasonable terms, or at all;
- we and certain of our licensees, partners, contracted organizations or independent investigators may have failed to effectively conduct clinical development or clinical manufacturing activities;
- the pathway to regulatory approval or reimbursement for product candidates was uncertain or not well-defined;
- the biosimilar product candidate failed to demonstrate the requisite biosimilarity to the applicable reference product, or was otherwise determined by a regulatory authority to not meet applicable standards for approval; and
- a companion diagnostic device that is required with the use of a product candidate is not approved by the necessary regulatory authority.

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

A number of our product candidates have failed or been discontinued at various stages in the product development process. For example, in 2015, we terminated our participation in the co-development and commercialization of brodalumab, a product candidate that was in phase 3, with AstraZeneca. The decision was based on events of suicidal ideation and behavior in the brodalumab program that occurred late in the development program, which we believed likely would necessitate restrictive labeling that would limit the appropriate patient population. Inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product for any of the reasons discussed could potentially have a negative effect on our product sales and earnings and could result in a significant impairment of in-process research and development (IPR&D) or other intangible assets.

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

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

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

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

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

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

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a risk management plan for our product or for approval of a new indication. For example, in connection with the June 2011 ESA label changes, we agreed to and conducted additional clinical trials examining the use of ESAs in CKD. Additional clinical trials we initiate, including those required by the FDA, could result in substantial additional expense, and the outcomes could result in further label restrictions or the loss of regulatory approval for an approved indication, each of which could have a material adverse effect on our product sales, business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our products, our business and results of operations.

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

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

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

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

Some of our products have been approved by U.S. and foreign regulatory authorities on an accelerated or conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, in March 2018, we announced that the FDA approved BLINCYTO® under accelerated approval for the treatment of adults and children with B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with MRD greater than or equal to 0.1 percent. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Regulatory authorities are placing greater focus on monitoring products originally approved on an accelerated or conditional basis and on whether the sponsors of such products have met the conditions of the accelerated or conditional approvals. If we are unable to fulfill the regulators' requirements that were conditions of a product's accelerated or conditional approval and/or if regulators reevaluate the data or risk-benefit profile of our product, the conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change the product's labeled indications or even withdraw the product from the market.

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

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

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

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

In addition to our innovative products, we are working to develop and commercialize biosimilar versions of a number of products currently manufactured, marketed and sold by other pharmaceutical companies. In some markets, there is not yet a legislative or regulatory pathway for the approval of biosimilars. In the United States, the BPCIA provided for such a pathway; while the FDA continues to implement it, discussions continue as to the evidence needed to demonstrate biosimilarity or interchangeability for specific products. See *We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.* Delays or uncertainties in the development or implementation of such pathways could result in delays or difficulties in getting our biosimilar products approved by regulatory authorities, subject us to unanticipated development costs or otherwise reduce the value of the investments we have made in the biosimilars area. Further, we cannot predict whether any repeal or reform of the ACA or other legislation or policy initiatives would affect the biosimilar pathway or have a material adverse effect on our development of biosimilars or on our marketed biosimilars. In addition, if we are unable to bring our biosimilar products to market on a timely basis and secure "first-to-market" or other advantageous positions, our future biosimilar sales, business and results of operations could be materially and adversely affected.

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

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

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

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

Failures by these parties to meet their contractual, regulatory, or other obligations to us or any disruption in the relationships between us and these third parties, could have a material adverse effect on our pharmaceutical pipeline and business. In addition, our collaborative relationships for R&D and/or commercialization and sales often extend for many years and have given, and may in the future give, rise to disputes regarding the relative rights, obligations and revenues of us and our collaboration partners, including the ownership or prosecution of intellectual property and associated rights and obligations. This could result in the loss of intellectual property rights or protection, delay the development and sale of potential pharmaceutical products, affect the effective sale and delivery of our commercialized products and lead to lengthy and expensive litigation, administrative proceedings or arbitration. For example, we are currently involved in litigation with Novartis over our collaboration agreements for the development and commercialization of Aimovig®. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. While our collaboration remains in place until the litigation is resolved and we remain committed to continuing to work with Novartis to sell and deliver Aimovig®, it is possible that the dispute may nevertheless affect the efficiency of operation and future growth of the collaboration. The litigation may also affect or delay, or lead to a termination of, other projects with Novartis.

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

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

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

RISKS RELATED TO OPERATIONS

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

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

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

In addition, we currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico. In recent years, Puerto Rico has been affected by natural disasters, including droughts in mid-2020, earthquakes in early 2020 and Hurricane Maria in 2017. These natural disasters have affected, and may continue to affect, public and private properties and Puerto Rico's electric grid and communications networks in the future. While the critical manufacturing areas of our commercial manufacturing facility were not significantly affected by these natural disasters, the restoration of electrical service on the island after Hurricane Maria was a slow process, and our facility operated with electrical power from backup diesel powered generators for some time. We also operated on backup generators for a few weeks after the early 2020 earthquakes in Puerto Rico. Further instability of the electric grid could require us to increase the use of our generators or to continue using them exclusively. In addition, future storms, earthquakes or other natural disasters or events could cause a more significant effect on our manufacturing operations. Puerto Rico and the rest of the world are facing the effects of the COVID-19 pandemic and the associated health and economic implications. Since March2020, the Governor of Puerto Rico issued Executive Orders requiring the lockdown of businesses and government facilities, imposing restrictions on business operations and a curfew on residents. Our operations and employees have been exempted from the lockdown and curfew, but we cannot predict how long these orders will continue in effect and what impact these orders and the COVID-19 pandemic will have on our future operations, and whether the Governor will issue future Executive Orders imposing stricter lockdown and curfew measures should COVID-19 cases rise in Puerto Rico. Although our ability to manufacture and supply our products has not, to date, been significantly affected by these natural disasters or the COVID-19 pandemic, a combination of these challenges or other issues that could give rise to any substantial disruption to our ability to operate our Puerto Rico manufacturing facility or get supplies and manufactured products transported to and from that location could materially and adversely affect our ability to supply our products and affect our product sales. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

Hurricane Maria, the earthquakes of early 2020 and the COVID-19 pandemic have placed greater stress on the island's already challenged economy. Beginning in 2016, the government of Puerto Rico defaulted on its roughly $72 billion in debt. In response, the U.S. Congress passed the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA), which established a Financial Oversight and Management Board (Oversight Board) to provide fiscal oversight. Title III of PROMESA provides Puerto Rico with a judicial process for restructuring its debt similar to, but not identical to, Chapter 9 of the U.S. Bankruptcy Code, including a stay of debtholder litigation. In 2017, the Oversight Board approved and certified the filing in the U.S. District Court for the District of Puerto Rico of a voluntary petition under Title III of PROMESA for the government of Puerto Rico and certain of its governmental entities, including the Puerto Rico Electric Power Authority, which is currently undergoing a privatization process of its transmission and distribution infrastructure. Under PROMESA, other Title III filings for additional government entities may occur, further complicating Puerto Rico's already uncertain fiscal stability. In June 2019, in response to legal challenges, the U.S. Supreme Court ruled in favor of PROMESA and confirmed the constitutionality of the appointment process.

Each year since 2017, the Oversight Board has updated Puerto Rico's fiscal plans imposing significant expense reductions. Each plan has stressed the need for fiscal and structural reforms to address Puerto Rico's challenging economic and demographic trends. There is pending litigation between the Government of Puerto Rico and the Oversight Board with regards to the Oversight Board's powers under PROMESA and authority to review and prevent the enforcement of government-approved legislation. This litigation, currently underway in the Title III Court, may impact how and when Puerto Rico will eventually restructure its debt and achieve fiscal and economic stability.

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

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

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

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

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

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

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

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

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

- capacity of manufacturing facilities;
- contamination by microorganisms or viruses, or foreign particles from the manufacturing process;

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

If any of these or other problems affect production in one or more of our facilities or those of our third-party contract manufacturers, or if we do not accurately forecast demand for our products or the amount of our product candidates required in clinical trials, we may be unable to start or increase production in our unaffected facilities to meet demand. If the efficient manufacture and supply of our products or product candidates is interrupted, we may experience delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends, contract disputes and/or recalls of our products. From time to time we have initiated recalls of certain lots of our products. For example, in July 2014 we initiated a voluntary recall of an Aranesp® lot distributed in the EU after particles were detected in a quality control sample following distribution of that lot, and in April 2018 we initiated a precautionary recall of two batches of Vectibix® distributed in Switzerland after potential crimping defects were discovered in the metal seals on some product vials. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could have a material adverse effect on our product sales, business and results of operations.

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

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

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

GENERAL RISK FACTORS

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

Our operations and performance have been, and may continue to be, affected by global economic conditions. The economic downturn resulting from the COVID-19 pandemic has precipitated a global recession which may be of an extended duration. Additionally, financial pressures may cause government or other third-party payers to more aggressively seek cost containment measures. See *Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability*. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships may also affect patients' ability to afford health care as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to reduced demand for our products, which could have a material adverse effect on our product sales, business and results of operations. Economic conditions may also adversely affect the ability of our distributors, customers and suppliers to obtain the liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Although we monitor our distributors', customers' and suppliers' financial condition and their liquidity to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could have a material adverse effect on our product sales, business and results of operations. A significant worsening of global economic conditions could materially increase these risks facing us.

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

Our stock price is volatile.

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

As of December 31, 2020, we owned or leased approximately 180 properties. The locations and primary functions of significant properties are summarized in the following tables:

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

* Corporate headquarters

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

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

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

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

Item 3. LEGAL PROCEEDINGS

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

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

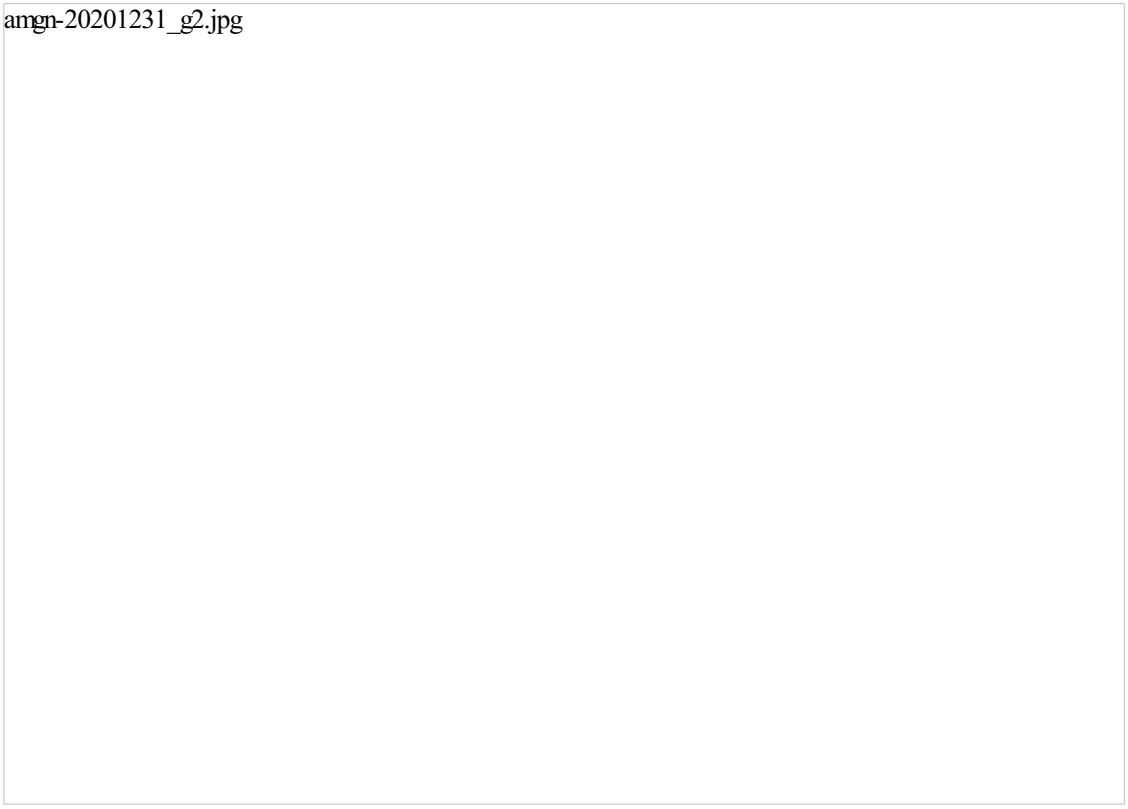
Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Common stock

Our common stock trades on the NASDAQ Global Select Market under the symbol AMGN. As of February 3, 2021, there were approximately 5,336 holders of record of our common stock.

Performance graph

The following graph shows the value of an investment of $100 on December 31, 2015, in each of Amgen common stock, the Amex Biotech Index, the Amex Pharmaceutical Index and Standard & Poor's 500 Index (S&P 500). All values assume reinvestment of the pretax value of dividends and are calculated as of December 31 of each year. The historical stock price performance of the Company's common stock shown in the performance graph is not necessarily indicative of future stock price performance.



	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020
Amgen (AMGN)	$100.00	$92.45	$113.08	$130.14	$166.09	$162.76
Amex Biotech (BTK)	$100.00	$80.85	$111.42	$111.72	$134.54	$152.81
Amex Pharmaceutical (DRG)	$100.00	$91.66	$106.90	$114.86	$135.96	$147.86
S&P 500 (SPX)	$100.00	$111.95	$136.46	$130.50	$171.57	$203.12

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

Stock repurchase program

During the three months and year ended December 31, 2020, we had one outstanding stock repurchase program, under which the repurchasing activity was as follows:

	Total number of shares purchased	Average price paid per share[1]	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program[2]
October 1 - October 31	1,774,922	$ 235.06	1,774,922	$ 3,781,230,811
November 1 - November 30	1,660,605	$ 229.16	1,660,605	$ 3,400,688,112
December 1 - December 31	1,868,786	$ 226.94	1,868,786	$ 2,976,579,948
	5,304,313	$ 230.35	5,304,313	
January 1 - December 31	15,190,194	$ 230.24	15,190,194	

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

(2) In December 2019, our Board of Directors increased the amount authorized under the stock repurchase program by an additional $4.0 billion.

Dividends

For the years ended December 31, 2020 and 2019, we paid quarterly dividends. We expect to continue to pay quarterly dividends, although the amount and timing of any future dividends are subject to approval by our Board of Directors. Additional information required by this item is incorporated herein by reference to Part IV—Note 16, Stockholders' equity, to the Consolidated Financial Statements.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

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

Item 6. SELECTED FINANCIAL DATA

Consolidated Statements of Income Data:	Years ended December 31, 2020	2019	2018	2017	2016
	(In millions, except per-share data)				
Revenues:					
Product sales	$ 24,240	$ 22,204	$ 22,533	$ 21,795	$ 21,892
Other revenues	1,184	1,158	1,214	1,054	1,099
Total revenues	$ 25,424	$ 23,362	$ 23,747	$ 22,849	$ 22,991
Operating expenses:					
Cost of sales	$ 6,159	$ 4,356	$ 4,101	$ 4,069	$ 4,162
Research and development	$ 4,207	$ 4,116	$ 3,737	$ 3,562	$ 3,840
Selling, general and administrative	$ 5,730	$ 5,150	$ 5,332	$ 4,870	$ 5,062
Net income[1]	$ 7,264	$ 7,842	$ 8,394	$ 1,979	$ 7,722
Diluted earnings per share[1]	$ 12.31	$ 12.88	$ 12.62	$ 2.69	$ 10.24
Dividends paid per share	$ 6.40	$ 5.80	$ 5.28	$ 4.60	$ 4.00

Consolidated Balance Sheets Data:	As of December 31, 2020	2019	2018	2017	2016
	(In millions)				
Total assets	$ 62,948	$ 59,707	$ 66,416	$ 79,954	$ 77,626
Total debt[2]	$ 32,986	$ 29,903	$ 33,929	$ 35,342	$ 34,596
Total stockholders' equity[3]	$ 9,409	$ 9,673	$ 12,500	$ 25,241	$ 29,875

(1) In 2017, we recorded a net charge of $6.1 billion as a result of the 2017 Tax Act.

(2) See Part IV—Note 15, Financing arrangements, to the Consolidated Financial Statements, for discussion of our financing arrangements in 2020, 2019 and 2018. In 2017, we issued $4.5 billion of debt and repaid $4.4 billion of debt. In 2016, we issued $7.3 billion of debt and repaid $3.7 billion of debt.

(3) Throughout the five years ended December 31, 2020, we had a stock repurchase program authorized by the Board of Directors, through which we repurchased $3.5 billion, $7.6 billion, $17.9 billion, $3.1 billion and $3.0 billion, respectively, of Amgen common stock.

In addition to the above notes, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, Part IV—Consolidated Financial Statements and accompanying notes as well as previously filed Annual Reports on Form 10-K for further information regarding our consolidated results of operations and financial position for periods reported therein and for known factors that will affect the comparability of future results. Also see Part IV—Note 16, Stockholders' equity, to the Consolidated Financial Statements, for information regarding cash dividends declared per share of common stock for each of the four quarters of 2020, 2019 and 2018. In addition, our Board of Directors declared dividends per share of $1.15 and $1.00, which were paid in each of the four quarters of 2017 and 2016, respectively.

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

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

Forward-looking statements

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

Overview

Amgen is a biotechnology company committed to unlocking the potential of biology for patients suffering from serious illnesses. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential. In 2020, we celebrated our 40th anniversary, continuing our history of focusing on innovative medicines that have the potential to be first-in-class molecules and that have a large-effect size on serious diseases.

Our principal products—those with the most significant annual commercial sales—are ENBREL, Prolia®, Neulasta®, Otezla®, XGEVA®, Aranesp®, KYPROLIS® and Repatha®. We also market a number of other products, including Nplate®, Vectibix®, MVASI®, Parsabiv®, EPOGEN®, KANJINTI®, BLINCYTO®, Aimovig®, EVENITY®, AMGEVITA™, Sensipar®/Mimpara®, NEUPOGEN®, IMLYGIC®, Corlanor® and AVSOLA®. For additional information about our products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products.

Our strategy includes integrated activities intended to maintain and strengthen our competitive position in the industry. We focus on six commercial areas: inflammation, oncology/hematology, bone health, CV disease, nephrology and neuroscience, and we conduct discovery research primarily in three therapeutic areas: inflammation, oncology/hematology and CV/metabolic diseases. In 2020, we advanced our innovative pipeline, successfully integrated Otezla®, acquired in November 2019, into our inflammation portfolio, advanced our international expansion and continued to provide uninterrupted supply of our medicines globally through the COVID-19 pandemic. We accomplished these objectives while maintaining a strategic and disciplined approach to capital allocation, and advancing our environmental, social and governance efforts.

During the year, while meeting the challenges of a global pandemic and facing increased competition from biosimilars and generics, total product sales increased 9%, driven by volume growth primarily from Otezla®, partially offset by lower net selling prices. Product sales increased 9% and 10% in the United States and rest of the world, respectively. Total operating expenses increased 19%, driven by expenses related to Otezla®.

We continued to advance our pipeline, including sotorasib and tezepelumab—two molecules with respect to which we have achieved positive registration enabling data from our clinical trial activities. We also continued to advance our biosimilar program with the launch of AVSOLA® and the approval of RIABNI™ in the United States. Our biosimilars are expected to launch in new markets throughout 2021. Lastly, we broadened our international reach, particularly in the Asia Pacific region with our investment in and strategic collaboration with BeiGene to expand our oncology presence in China, as well as the establishment of our wholly owned affiliate in Japan.

Cash flows from operating activities totaled $10.5 billion, enabling us to invest in our business while returning capital to shareholders through the payment of cash dividends and stock repurchases. For 2020, we increased our quarterly cash dividend by 10% to $1.60 per share of common stock. In December 2020, we declared a cash dividend of $1.76 per share of common stock for the first quarter of 2021, an increase of 10% for this period, to be paid in March 2021. We also repurchased 15.2 million shares of our common stock throughout 2020, at an aggregate cost of $3.5 billion. During the year, we had proceeds from the issuance of debt of $8.9 billion and repayments of debt of $6.5 billion. In addition, we exchanged some of our higher interest rate debt for newly issued debt with a lower interest rate and a later maturity date.

Amgen's approach to, and investment in, human capital resource management is directed at attracting, motivating and retaining talent to tackle the challenges of running an enterprise focused on the discovery, development, and commercialization of innovative medicines. Our compensation, benefits and development programs are designed to encourage performance, promote accountability and adherence to Company values, and in alignment with the interests of the Company's shareholders. Further, we believe that a diverse and inclusive culture fosters innovation, which supports our ability to serve patients. We also believe our global presence is strengthened by having a workforce that reflects the diversity of the patients we serve. It is with these beliefs in mind that we have continued to strengthen and grow our culture of diversity, inclusion and belonging. Our internal efforts include, in 2019, establishing a Diversity, Inclusion and Belonging Council. We are engaging in activities and setting goals to improve our focus on diversity, inclusion and belonging. For further information on these and other efforts, see Part I, Item 1. Business—Human Capital Resources.

We have a long-standing ambition to be environmentally responsible, and we regularly set targets to challenge ourselves to deliver further improvements. In 2020, we met or exceeded our environmental sustainability targets set out in 2013 that called for reducing fleet carbon output by up to 20%, facility carbon output by 10%, water consumption by 10% and waste disposal by 35%[2]. We achieved our 2020 targets while growing revenues, increasing production capacity, and expanding to more than 100 countries over the same 2013 to 2020 period. To continue on our path to greater environmental sustainability, in January 2021 we announced a new set of long-term environmental targets to achieve by 2027, including achieving carbon neutrality, reducing water consumption by 40% and reducing waste disposed by 75%.

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

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

COVID-19 pandemic

The COVID-19 pandemic has had a moderate impact to our business in 2020. Since the onset of the pandemic in early 2020, we have been carefully monitoring its impact on our global operations. We have taken appropriate steps to minimize the risk to our employees. A significant number of our employees have been working remotely, with the exception of certain staff that require access to our manufacturing and laboratory research facilities, in accordance with applicable government health and safety protocols and guidance issued in response to the COVID-19 pandemic. To date, our remote working arrangements have not significantly affected our ability to maintain critical business operations, and we have not experienced disruptions or shortages of our supply of medicines.

Since the beginning of the COVID-19 pandemic, we have seen changes in demand trends for some of our products, including lower demand for certain products as continuing patient access to those products has been affected by COVID-19, particularly in the early phases of the pandemic. For example, near the end of March, we began to observe a decline in sales of Prolia®, as elderly patients, who are relatively more vulnerable to COVID-19, avoided doctors' offices. Demand has since recovered to varying degrees by product as local conditions improved in certain geographies that opened after an initial improvement in COVID-19 infection rates, allowing patients to resume receiving their treatments. During the second half of the year, our own efforts remain focused on assisting patients with improving their continuity of care to increase product access as compared to what they experienced during the earlier stages of the pandemic. Recently, higher rates of infection have been observed in certain geographies, including the United States and Europe, which may further restrict demand, similar to early phases of the pandemic. As a result, we expect to see continued volatility through at least the duration of the pandemic as governments respond to current local conditions.

[2] Represents reductions against established baselines, taking into account only verified reduction projects, and does not take into account changes associated with contraction or expansion of the company.

The majority of clinical trials that were paused at the onset of the pandemic to ensure subject safety or data integrity have resumed. Study enrollment was affected negatively the most in the second quarter of the year and by the end of 2020 resumed to around pre-pandemic levels. However, going forward COVID-19 infection rates and related vaccination activities may impact future study enrollment. We continuously monitor our ability for study enrollment on an institution by institution basis and reevaluate the status of studies, pausing when uncertainty arises with regard to the trial sites' ability to ensure safety or data integrity. We remain focused on supporting our active clinical sites in providing care for these patients and in providing investigational drug supply. In addition, our R&D organization is supporting efforts to combat the COVID-19 pandemic in a number of ways, including by (i) working to support production of therapeutic antibodies that could diminish the impact of COVID-19 on patients, (ii) joining a public–private partnership between leading companies in our industry and U.S. government health agencies to develop a strategy for a coordinated research response and (iii) participating in platform studies to investigate treatments in adult patients hospitalized with severe COVID-19 infections.

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

Selected Financial Information

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019
Product sales:			
U.S.	$ 17,985	9 %	$ 16,531
Rest-of-world (ROW)	6,255	10 %	5,673
Total product sales	24,240	9 %	22,204
Other revenues	1,184	2 %	1,158
Total revenues	$ 25,424	9 %	$ 23,362
Operating expenses	$ 16,285	19 %	$ 13,688
Operating income	$ 9,139	(6) %	$ 9,674
Net income	$ 7,264	(7) %	$ 7,842
Diluted EPS	$ 12.31	(4) %	$ 12.88
Diluted shares	590	(3) %	609

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

Total product sales increased for 2020, primarily driven by unit demand increases from newer brands including Otezla®, acquired in November 2019, MVASI®, KANJINTI® and Repatha®. These unit demand increases were partially offset by declines in net selling prices for certain products, unit demand declines for mature brands that face biosimilar or generic competition and the effects of the COVID-19 pandemic. For 2021, we expect that net selling prices will continue to decline. We also expect increasing competition against our biosimilar products. Further, the first quarter historically represents the lowest product sales quarter for the year, in part, due to plan changes, insurance reverifications and higher co-pay expenses as U.S. patients work through deductibles, particularly for our pharmacy benefit products.

During the initial stages of the COVID-19 pandemic, we experienced changes in demand trends for some of our products. The pandemic interrupted many physician–patient interactions, which led to delays in diagnosis and treatment, with varying degrees of impact across our portfolio. In general, sales of negatively affected products fell the most in the early part of the second quarter, with product demand beginning to show some recovery in the second half of the year but still below pre-pandemic levels. Nevertheless, given the increased intensity exiting 2020 and the unpredictable nature of the pandemic, we expect there could be intermittent disruptions in physician–patient interactions going forward, and thus we continue to expect quarter-to-quarter variability. See Part I, Item 1A. Risk Factors of this Form 10-K.

In addition, other changes in the healthcare ecosystem introduce variability into product sales trends. For example, changes in U.S. employment could lead to changes to the insured population, with growth in Medicaid enrollees and uninsured individuals having a negative impact on revenues. Overall, uncertainty has increased around the timing and magnitude of our sales during the COVID-19 pandemic.

Other revenues increased for 2020, primarily driven by higher royalties.

Operating expenses increased for 2020, primarily driven by acquisition- and commercial-related expenses for Otezla®.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is partially offset by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material in 2020, 2019 or 2018.

Results of Operations

Product sales

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
ENBREL	$ 4,996	(4) %	$ 5,226	4 %	$ 5,014
Prolia®	2,763	3 %	2,672	17 %	2,291
Neulasta®	2,293	(29) %	3,221	(28) %	4,475
Otezla®	2,195	*	178	N/A	—
XGEVA®	1,899	(2) %	1,935	8 %	1,786
Aranesp®	1,568	(9) %	1,729	(8) %	1,877
KYPROLIS®	1,065	2 %	1,044	8 %	968
Repatha®	887	34 %	661	20 %	550
Other products	6,574	19 %	5,538	(1) %	5,572
Total product sales	$ 24,240	9 %	$ 22,204	(1) %	$ 22,533
Total U.S.	$ 17,985	9 %	$ 16,531	(5) %	$ 17,429
Total ROW	6,255	10 %	5,673	11 %	5,104
Total product sales	$ 24,240	9 %	$ 22,204	(1) %	$ 22,533

* Change in excess of 100%.

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

ENBREL

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
ENBREL — U.S.	$ 4,855	(4) %	$ 5,050	5 %	$ 4,807
ENBREL — Canada	141	(20) %	176	(15) %	207
Total ENBREL	$ 4,996	(4) %	$ 5,226	4 %	$ 5,014

The decrease in ENBREL sales for 2020 was driven by lower unit demand and net selling price, partially offset by favorable changes to estimated sales deductions and inventory. Consistent with prior periods, ENBREL has continued to lose market share, and this decline has been compounded by a reduction in the growth rate of the rheumatology market as a result of COVID-19. For 2021, we expect ENBREL to follow the historic pattern of lower sales in the first quarter relative to subsequent quarters due to the impact of benefit plan changes, insurance reverification and increase co-pay expenses as U.S. patients work through deductibles. In addition, for 2021, we expect volume and net selling price declines to continue.

The increase in ENBREL sales for 2019 was primarily driven by favorable changes to estimated sales deductions and an increase in net selling price, partially offset by lower unit demand.

In April 2019, the FDA approved a second biosimilar version of ENBREL, and we are involved in patent litigations with the two companies seeking to market their FDA-approved biosimilar versions of ENBREL. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. Companies with approved biosimilar versions of ENBREL may seek to enter the U.S. market if we are not successful in our litigations, or even earlier. Other companies are also developing proposed biosimilar versions of ENBREL.

Prolia®

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Prolia® — U.S.	$ 1,830	3 %	$ 1,772	18 %	$ 1,500
Prolia® — ROW	933	4 %	900	14 %	791
Total Prolia®	$ 2,763	3 %	$ 2,672	17 %	$ 2,291

Disruptions in patient visits as a result of the COVID-19 pandemic affected demand during 2020 by altering the timing of patients receiving their semiannual doses and by lowering the diagnosis of osteoporosis in new patients. This deceleration of demand has softened the historical growth rates and altered demand patterns of Prolia® experienced in years prior to the pandemic. For 2021, historical demand patterns may continue to be impacted by the pandemic.

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

The increase in global Prolia® sales for 2019 was driven by higher unit demand.

Neulasta®

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Neulasta® — U.S.	$ 2,001	(29) %	$ 2,814	(27) %	$ 3,866
Neulasta® — ROW	292	(28) %	407	(33) %	609
Total Neulasta®	$ 2,293	(29) %	$ 3,221	(28) %	$ 4,475

The decreases in global Neulasta® sales for 2020 and 2019 were driven by the impact of biosimilar competition on net selling price and unit demand. Neulasta® sales included a $98 million order from the U.S. government in the first quarter of 2019.

We have increased competition in the United States and Europe as a result of biosimilar versions of Neulasta®, which has had and will continue to have a material adverse impact on sales. We also expect other biosimilar versions to be approved in the future. For a discussion of ongoing patent litigations related to these and other biosimilars, see Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements.

Otezla®

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Otezla® — U.S.	$ 1,790	*	$ 139	N/A	$ —
Otezla® — ROW	405	*	39	N/A	—
Total Otezla®	$ 2,195	*	$ 178	N/A	$ —

* Change in excess of 100%.

Otezla® was acquired on November 21, 2019, and generated $2.2 billion and $178 million in global sales for the years ended December 31, 2020 and 2019, respectively. For 2021, we expect Otezla® to follow the historic pattern of lower sales in the first quarter relative to subsequent quarters due to the impact of benefit plan changes, insurance reverification and increase co-pay expenses as U.S. patients work through deductibles.

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

XGEVA®

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
XGEVA® — U.S.	$ 1,405	(4) %	$ 1,457	9 %	$ 1,338
XGEVA® — ROW	494	3 %	478	7 %	448
Total XGEVA®	$ 1,899	(2) %	$ 1,935	8 %	$ 1,786

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

The increase in global XGEVA® sales for 2019 was primarily driven by higher unit demand.

Aranesp®

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Aranesp® — U.S.	$ 629	(17) %	$ 758	(20) %	$ 942
Aranesp® — ROW	939	(3) %	971	4 %	935
Total Aranesp®	$ 1,568	(9) %	$ 1,729	(8) %	$ 1,877

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

The decrease in global Aranesp® sales for 2019 was primarily driven by the impact of competition on unit demand in the United States.

Aranesp® faces competition from a long-acting ESA. Aranesp® also faces competition from a biosimilar version of EPOGEN®. For 2021, we expect that sales will continue to decline due to short- and long-acting competition.

KYPROLIS®

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
KYPROLIS® — U.S.	$ 710	9 %	$ 654	12 %	$ 583
KYPROLIS® — ROW	355	(9) %	390	1 %	385
Total KYPROLIS®	$ 1,065	2 %	$ 1,044	8 %	$ 968

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

The increase in global KYPROLIS® sales for 2019 was primarily driven by higher unit demand.

We are engaged in litigation with two companies that are challenging certain of our patents related to KYPROLIS® and that are seeking to market generic carfilzomib products. Separately, we have entered into confidential settlement agreements with other companies developing generic carfilzomib products, and the court has entered consent judgments enjoining those companies from infringing certain of our patents, subject to terms of the confidential settlement agreements. See Part IV—Note 19, Contingencies and commitments, to the Consolidated Financial Statements. The FDA reported that it has granted tentative or final approval to Abbreviated New Drug Applications (ANDAs) for generic carfilzomib products filed by a number of companies for generic carfilzomib products. The date of approval of those ANDAs for generic carfilzomib products is governed by the Hatch-Waxman Act and any applicable settlement agreements between the parties.

Repatha®

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Repatha® — U.S.	$ 459	22 %	$ 376	5 %	$ 358
Repatha® — ROW	428	50 %	285	48 %	192
Total Repatha®	$ 887	34 %	$ 661	20 %	$ 550

The increases in global Repatha® sales for 2020 and 2019 were driven by higher unit demand, partially offset by lower net selling price. The decrease to the Repatha® net selling price in 2020 was the result of contracting changes to improve Medicare Part D patient access.

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

Other products

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Nplate® — U.S.	$ 485	1 %	$ 480	10 %	$ 438
Nplate® — ROW	365	16 %	315	13 %	279
Vectibix® — U.S.	342	8 %	316	10 %	288
Vectibix® — ROW	469	10 %	428	6 %	403
MVASI® — U.S.	656	*	121	N/A	—
MVASI® — ROW	142	*	6	N/A	—
Parsabiv® — U.S.	605	10 %	550	82 %	302
Parsabiv® — ROW	111	39 %	80	*	34
EPOGEN® — U.S.	598	(31) %	867	(14) %	1,010
KANJINTI® — U.S.	475	*	118	N/A	—
KANJINTI® — ROW	92	(15) %	108	*	44
BLINCYTO® — U.S.	231	31 %	176	31 %	134
BLINCYTO® — ROW	148	9 %	136	42 %	96
Aimovig® — U.S.	378	24 %	306	*	119
EVENITY® — U.S.	191	*	42	N/A	—
EVENITY® — ROW	159	8 %	147	N/A	—
AMGEVITA™ — ROW	331	54 %	215	*	11
Sensipar® — U.S.	92	(63) %	252	(82) %	1,436
Sensipar®/Mimpara® — ROW	196	(34) %	299	(12) %	338
NEUPOGEN® — U.S.	144	(19) %	178	(20) %	223
NEUPOGEN® — ROW	81	(6) %	86	(39) %	142
Other — U.S.	109	4 %	105	24 %	85
Other — ROW	174	(16) %	207	9 %	190
Total other product sales	$ 6,574	19 %	$ 5,538	(1) %	$ 5,572
Total U.S. — other products	$ 4,306	23 %	$ 3,511	(13) %	$ 4,035
Total ROW — other products	2,268	12 %	2,027	32 %	1,537
Total other product sales	$ 6,574	19 %	$ 5,538	(1) %	$ 5,572

* Change in excess of 100%.

Operating expenses

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

	Year ended December 31, 2020	Change	Year ended December 31, 2019	Change	Year ended December 31, 2018
Operating expenses:					
Cost of sales	$ 6,159	41 %	$ 4,356	6 %	$ 4,101
% of product sales	25.4 %		19.6 %		18.2 %
% of total revenues	24.2 %		18.6 %		17.3 %
Research and development	$ 4,207	2 %	$ 4,116	10 %	$ 3,737
% of product sales	17.4 %		18.5 %		16.6 %
% of total revenues	16.5 %		17.6 %		15.7 %
Selling, general and administrative	$ 5,730	11 %	$ 5,150	(3) %	$ 5,332
% of product sales	23.6 %		23.2 %		23.7 %
% of total revenues	22.5 %		22.0 %		22.5 %
Other	$ 189	*	$ 66	(79) %	$ 314

* Change in excess of 100%.

Cost of sales

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

Cost of sales increased to 18.6% of total revenues for 2019, primarily driven by unfavorable product mix and amortization of intangible assets as a result of our acquisition of Otezla®, partially offset by lower royalties and lower manufacturing costs.

Research and development

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

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

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

	Years ended December 31,		
	2020	2019	2018
Research and early pipeline	$ 1,405	$ 1,649	$ 1,201
Later-stage clinical programs	1,365	1,062	1,034
Marketed products	1,437	1,405	1,502
Total R&D expense	$ 4,207	$ 4,116	$ 3,737

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

The increase in R&D expense for 2019 was primarily driven by higher spend in research and early pipeline in support of our oncology programs, partially offset by lower marketed-product support.

Selling, general and administrative

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

The decrease in SG&A expense for 2019 was primarily driven by lower general and administrative expenses, the end of certain amortization charges in 2018 and lower spend for launched and marketed products, partially offset by spending for Otezla® commercial-related expenses.

Other

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

Other operating expenses for 2019 included $47 million in restructuring costs.

Other operating expenses for 2018 included a $330 million impairment charge associated with an IPR&D asset and a $42 million favorable net change in the fair values of contingent consideration liabilities. See Part IV—Note 17, Fair value measurement, to the Consolidated Financial Statements.

Nonoperating expenses/income and income taxes

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

	Years ended December 31,		
	2020	2019	2018
Interest expense, net	$ 1,262	$ 1,289	$ 1,392
Interest and other income, net	$ 256	$ 753	$ 674
Provision for income taxes	$ 869	$ 1,296	$ 1,151
Effective tax rate	10.7 %	14.2 %	12.1 %

Interest expense, net

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

The decrease in Interest expense, net, for 2019 was primarily due to a reduction in outstanding long-term debt as a result of maturities in 2019.

Interest and other income, net

The decrease in Interest and other income, net, for 2020 was primarily due to reduced interest income as a result of lower average cash balances and a decline in interest yields and losses incurred in connection with our BeiGene investment, partially offset by gains recognized on our investments in publicly traded equity securities and limited partnerships. We may continue to recognize losses in connection with our BeiGene investment in 2021. See Part IV—Note 9, Investments, to the Consolidated Financial Statements.

The increase in Interest and other income, net, for 2019 was primarily due to net gains on sales of investments in interest-bearing securities liquidated to fund our acquisition of Otezla® and our investment in BeiGene compared with losses in the prior year, partially offset by reduced interest income as a result of lower average cash balances and a gain recognized in connection with our acquisition of Kirin-Amgen, Inc. (K-A), in the first quarter of 2018. See Part IV—Note 2, Acquisitions, to the Consolidated Financial Statements.

Income taxes

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

The increase in our effective tax rate for 2019 compared with 2018 was primarily driven by a prior-year tax benefit associated with intercompany sales under U.S. corporate tax reform.

In March and December 2020, in response to the COVID-19 pandemic, the CARES Act and the Consolidated Appropriations Act, 2021, were passed into law and provide additional economic stimulus to address the impact of the COVID-19 pandemic. We do not expect any significant benefit to our income tax provision as a result of this legislation.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010, 2011 and 2012 proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. However, we have been unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a Notice of Deficiency which we would expect to vigorously contest through the judicial process. In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagree with the 2013, 2014 and 2015 proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. The IRS audit for years 2016, 2017 and 2018 is expected to start in the near term. We are also currently under examination by a number of other state and foreign tax jurisdictions.

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

See Summary of Critical Accounting Policies—Income taxes, and Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

Financial Condition, Liquidity and Capital Resources

Selected financial data was as follows (in millions):

	December 31,	
	2020	2019
Cash, cash equivalents and marketable securities	$ 10,647	$ 8,911
Total assets	$ 62,948	$ 59,707
Current portion of long-term debt	$ 91	$ 2,953
Long-term debt	$ 32,895	$ 26,950
Stockholders' equity	$ 9,409	$ 9,673

Cash, cash equivalents and marketable securities

We have global access to our $10.6 billion balance of cash, cash equivalents and marketable securities. The primary objective of our investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

Capital allocation

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

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

The Board of Directors declared quarterly cash dividends of $1.60, $1.45 and $1.32 per share of common stock paid in 2020, 2019 and 2018, respectively, an increase of 10% over the prior year in both 2020 and 2019. In December 2020, the Board of Directors declared a cash dividend of $1.76 per share of common stock for the first quarter of 2021, an increase of 10% for this period, to be paid in March 2021.

We also returned capital to stockholders through our stock repurchase program. During 2020, we repurchased $3.5 billion of common stock and had cash settlements of $3.5 billion. In 2019, we repurchased $7.6 billion of common stock and had cash settlements of $7.7 billion. In 2018, we repurchased $17.9 billion of common stock and had cash settlements of $17.8 billion, which included 52.1 million shares of common stock repurchased through a $10.0 billion tender offer. In May 2019 and December 2019, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $5.0 billion and $4.0 billion, respectively. As of December 31, 2020, $3.0 billion remained available under the stock repurchase program.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of December 31, 2020 and 2019. Our accumulated deficit is not anticipated to affect our future ability to operate, repurchase stock, pay dividends or repay our debt given our expected continued profitability and strong financial position.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital, capital expenditure and debt service requirements, our plans to pay dividends and repurchase stock and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt markets and equity markets. See Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business.*

Financing arrangements

The current and noncurrent portions of our long-term borrowings as of December 31, 2020, were $0.1 billion and $32.9 billion, respectively. The current and noncurrent portions of our long-term borrowings as of December 31, 2019, were $3.0 billion and $27.0 billion, respectively. The carrying values of our long-term borrowings are net of fair value adjustments for interest rate swaps and unamortized discounts, premiums and offering costs. As of December 31, 2020, Standard & Poor's Financial Services LLC (S&P), Moody's Investors Service, Inc. (Moody's) and Fitch Ratings, Inc. (Fitch), assigned credit ratings to our outstanding senior notes of A– with a stable outlook, Baa1 with a stable outlook and BBB+ with a stable outlook, respectively, which are considered investment grade. Unfavorable changes to these ratings may have an adverse impact on future financings.

During 2020, we issued debt with an aggregate principal amount of $9.0 billion. During 2019 and 2018, we did not issue any debt or debt securities. During 2020, 2019 and 2018, we repaid debt of $6.5 billion, $4.5 billion and $1.1 billion, respectively. In addition, during 2020, we exchanged $0.7 billion of certain of our outstanding note issuances with $0.9 billion of newly issued notes with a lower interest rate and later maturity date.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the lives of the respective notes. These interest rate swap contracts qualify and are designated as fair value hedges. As of December 31, 2020 and 2019, we had interest rate swap contracts with aggregate notional amounts of $5.9 billion and $9.6 billion, respectively.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts, which effectively convert the interest payments and principal repayment of the respective notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts qualify and are designated as cash flow hedges. As of both December 31, 2020 and 2019, we had cross-currency swap contracts with aggregate notional amounts of $4.8 billion.

As of December 31, 2020, we had a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. During 2020, 2019 and 2018, we did not issue any commercial paper. No commercial paper was outstanding as of December 31, 2020 and 2019.

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

It is anticipated that LIBOR will be phased out and replaced by 2023. While various replacement reference rates have been discussed, an alternative reference rate to LIBOR has not yet been widely adopted. Therefore, the mechanics to modify existing contracts that reference LIBOR have not been finalized. We are currently evaluating the impact that the change in the reference rate will have on our financial condition. See Part I, Item 1A. Risk Factors—*Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.*

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

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant that requires us to maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2020.

See Part IV—Note 15, Financing arrangements, and Note 18, Derivative instruments, to the Consolidated Financial Statements.

Cash flows

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

	Years ended December 31,		
	2020	2019	2018
Net cash provided by operating activities	$ 10,497	$ 9,150	$ 11,296
Net cash (used in) provided by investing activities	$ (5,401)	$ 5,709	$ 14,339
Net cash used in financing activities	$ (4,867)	$ (15,767)	$ (22,490)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities increased during 2020 primarily due to higher Net income after adding back the noncash amortization related to the acquisition of Otezla®, the monetization of interest rate swap contracts and working capital adjustments. Cash provided by operating activities decreased during 2019 primarily due to changes in working capital, an increase in payments to the IRS related to an advance deposit and lower Net income.

Investing

Cash used in investing activities during 2020 was primarily due to our $3.2 billion of purchases of equity method investments, primarily BeiGene, and net cash outflows related to marketable securities of $1.5 billion. Cash provided by investing activities during 2019 and 2018 was primarily due to net cash inflows related to marketable securities of $20.0 billion and $15.0 billion, respectively. The liquidation of portions of our marketable securities portfolio in 2019 was primarily the result of funding the acquisition of Otezla® and our investment in BeiGene and, in 2018, to fund our tender offer to repurchase our common stock. Capital expenditures were $608 million, $618 million and $738 million in 2020, 2019 and 2018, respectively. We currently estimate 2021 spending on capital projects to be approximately $900 million. A majority of the increase in expenditures relates to expansion of manufacturing capacity to enable supply of products and product candidates.

Financing

Cash used in financing activities during 2020 was primarily due to repayments of debt of $6.5 billion, the payment of dividends of $3.8 billion and payments to repurchase our common stock of $3.5 billion, partially offset by proceeds from issuance of debt of $8.9 billion. Cash used in financing activities during 2019 was primarily due to repurchases of our common stock of $7.7 billion, repayments of debt of $4.5 billion and payments of dividends of $3.5 billion. Cash used in financing activities during 2018 was primarily due to repurchases of common stock of $17.8 billion, payments of dividends of $3.5 billion and repayments of debt of $1.1 billion.

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

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are material or reasonably likely to become material to our consolidated financial position or consolidated results of operations.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent liabilities for which we cannot reasonably predict future payment. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information. Timing of payments and actual amounts paid may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations.

The following table represents our contractual obligations aggregated by type (in millions):

	Payments due by period as of December 31, 2020				
Contractual obligations	**Total**	**Year 1**	**Years 2 and 3**	**Years 4 and 5**	**Years 6 and beyond**
Long-term debt obligations[1][2]	$ 54,293	$ 1,207	$ 7,857	$ 4,944	$ 40,285
Operating lease obligations[3]	864	166	268	102	328
Purchase obligations[4]	2,697	2,129	375	121	72
U.S. repatriation tax[5]	5,575	587	1,687	3,301	—
Unrecognized tax benefits (UTBs)[6]	—	—	—	—	—
Total contractual obligations	$ 63,429	$ 4,089	$ 10,187	$ 8,468	$ 40,685

(1) Long-term debt obligations includes future interest payments on our fixed-rate obligations at the contractual coupon rates. To achieve a desired mix of fixed-rate and floating-rate debt, we enter into interest rate swap contracts that effectively convert a fixed-rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the terms of the related hedge contracts. We used an interest rate forward curve as of December 31, 2020, in computing net amounts to be paid or received under our interest rate swap contracts, which resulted in an aggregate net decrease in future interest payments of $67 million. See Part IV—Note 15, Financing arrangements, to the Consolidated Financial Statements.

(2) Long-term debt obligations includes contractual interest payments and principal repayments of our foreign-denominated debt obligations. In order to hedge our exposure to foreign currency exchange rate risk associated with our euro-, pound-sterling- and Swiss-franc-denominated long-term debt, we entered into cross-currency swap contracts that effectively converted interest payments and principal repayments on this debt from euros, pounds sterling and Swiss francs to U.S. dollars. For purposes of this table, we used the contracted exchange rates in the cross-currency swap contracts to compute the net amounts of future interest payments and principal repayments on this debt. See Part IV—Note 18, Derivative instruments, to the Consolidated Financial Statements.

(3) Operating lease obligations includes payments for leases that have not yet commenced, net of lease incentives, and excludes $107 million of future receipts under noncancelable subleases of abandoned facilities.

(4) Purchase obligations relates primarily to (i) R&D commitments (including those related to clinical trials) for new and existing products, (ii) capital expenditures and (iii) open purchase orders for the acquisition of goods and services in the ordinary course of business. Our obligation to pay certain of these amounts may be reduced based on certain future events.

(5) Under the 2017 Tax Act, we elected to pay in eight annual installments the repatriation tax related primarily to our prior indefinitely invested earnings of our foreign operations. See Part IV—Note 19, Contingencies and commitments—Commitments–U.S. repatriation tax, to the Consolidated Financial Statements.

(6) Liabilities for UTBs are not included in the table above because due to their nature there is a high degree of uncertainty regarding the timing of future cash outflows and other events that extinguish these liabilities. See Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

In addition to amounts in the table above, we are contractually obligated to pay additional amounts that in the aggregate are significant, upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties, including contingent consideration incurred in the acquisitions of K-A and BioVex Group Inc. (BioVex). These payments are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring. These contingent payments have not been included in the table above, and except with respect to the fair value of the contingent consideration obligations, are not recorded on our Consolidated Balance Sheets. As of December 31, 2020, the maximum amount that may be payable in the future for agreements we have entered into with third parties is $5.4 billion, including $250 million of contingent consideration payments in connection with the acquisition of BioVex.

Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

Product sales and sales deductions

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

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

	Rebates	Chargebacks	Other deductions	Total
Balance as of December 31, 2017	$ 1,867	$ 272	$ 108	$ 2,247
Amounts charged against product sales	6,180	6,926	1,180	14,286
Payments	(5,458)	(6,744)	(1,161)	(13,363)
Balance as of December 31, 2018	2,589	454	127	3,170
Amounts charged against product sales	6,825	7,090	1,292	15,207
Payments	(6,249)	(6,985)	(1,263)	(14,497)
Balance as of December 31, 2019	3,165	559	156	3,880
Amounts charged against product sales	9,167	8,223	1,818	19,208
Payments	(8,353)	(8,191)	(1,735)	(18,279)
Balance as of December 31, 2020	$ 3,979	$ 591	$ 239	$ 4,809

For the years ended December 31, 2020, 2019 and 2018, total sales deductions were 44%, 41% and 39% of gross product sales, respectively. The increase in the total sales deductions balance as of December 31, 2020, compared to December 31, 2019, was primarily driven by the increase in gross sales and the impact of higher U.S. commercial rebate rates. Included in the amounts are immaterial net adjustments related to prior-year sales due to changes in estimates. Such amounts represent less than 1% of the aggregate sales deductions charged against product sales in the years ended December 31, 2020, 2019 and 2018.

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

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

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

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

Product returns

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

Income taxes

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

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

Certain items are included in our tax return at different times than they are reflected in the financial statements, and they cause temporary differences between the tax bases of assets and liabilities and their reported amounts. Such temporary differences create deferred tax assets and liabilities. Deferred tax assets are generally items that can be used as a tax deduction or credit in the tax return in future years but for which we have already recorded the tax benefit in the consolidated financial statements. We establish valuation allowances against our deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities are either (i) tax expenses recognized in the consolidated financial statements for which payment has been deferred, (ii) expenses for which we have already taken a deduction on the tax return but have not yet recognized in the consolidated financial statements or (iii) liabilities for the difference between the book basis and tax basis of the intangible assets acquired in many business combinations, as future expenses associated with these assets most often will not be tax deductible.

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

As previously disclosed, in 2017 we received an RAR and a modified RAR from the IRS for the years 2010, 2011 and 2012 proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. However, we have been unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a Notice of Deficiency which we would expect to vigorously contest through the judicial process. In addition, in 2020 we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagree with the 2013, 2014 and 2015 proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. The IRS audit for years 2016, 2017 and 2018 is expected to start in the near term. We are also currently under examination by a number of other state and foreign tax jurisdictions. Final resolution of these complex matters is not likely within the next 12 months. We believe our accrual for income tax liabilities is appropriate based

on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our consolidated financial statements. See Part IV—Note 6, Income taxes, to the Consolidated Financial Statements.

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

Contingencies

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

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

Valuation of assets and liabilities in connection with acquisitions

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

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

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

Impairment of long-lived assets

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

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

Impairment of equity method investments

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

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

Recently Issued Accounting Standards

See Part IV—Note 1, Summary of significant accounting policies, to the Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 31, 2020.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

In the discussion that follows, we have assumed a hypothetical change in interest rates of 100 basis points from those as of December 31, 2020 and 2019. Except as noted below, we have also assumed a hypothetical 20% change in foreign currency exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2020 and 2019.

Interest-rate-sensitive financial instruments

Our portfolio of available-for-sale investments as of December 31, 2020 and 2019, was composed of U.S. Treasury securities and money market mutual funds, and with respect to investments as of December 31, 2019, corporate debt securities and other short-term interest-bearing securities. The fair values of our available-for-sale investments were $9.8 billion and $8.2 billion as of December 31, 2020 and 2019, respectively. Duration is a sensitivity measure that can be used to approximate the change in the value of a security that will result from a 100 basis point change in interest rates. Applying a duration model, a hypothetical 100 basis point increase in interest rates as of December 31, 2020 and 2019, would not have resulted in a material reduction in the fair values of these securities. In addition, a hypothetical 100 basis point decrease in interest rates as of December 31, 2020 and 2019, would not result in a material effect on income in the respective ensuing year.

As of December 31, 2020, we had outstanding debt with a carrying value of $33.0 billion and a fair value of $39.4 billion. As of December 31, 2019, we had outstanding debt with a carrying value of $29.9 billion and a fair value of $33.7 billion. Our outstanding debt was composed almost entirely of debt with fixed interest rates. Changes in interest rates do not affect interest expense on fixed-rate debt. Changes in interest rates would, however, affect the fair values of fixed-rate debt. A hypothetical 100 basis point decrease in interest rates relative to interest rates as of December 31, 2020 and 2019, would have resulted in increases of $4.5 billion and $3.0 billion, respectively, in the aggregate fair value of our outstanding debt on each of these dates. Analysis of the debt does not consider the impact that hypothetical changes in interest rates would have on the related interest rate swap contracts and cross-currency swap contracts, discussed below.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified and were designated for accounting purposes as fair value hedges for certain of our fixed-rate debt. These interest rate swap contracts effectively converted a fixed-rate interest coupon to a floating-rate LIBOR-based coupon over the life of the respective notes. Interest rate swap contracts with aggregate notional amounts of $5.9 billion and $9.6 billion were outstanding as of December 31, 2020 and 2019, respectively. A hypothetical 100 basis point increase in interest rates relative to interest rates as of December 31, 2020 and 2019, would have resulted in reductions in fair values of approximately $230 million and $380 million, respectively, on our interest rate swap contracts on these dates. Analysis of the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair values of debt that these interest-rate-sensitive instruments were designed to offset.

As of December 31, 2020 and 2019, we had outstanding cross-currency swap contracts with aggregate notional amounts of $4.8 billion that hedge our foreign-currency-denominated debt and related interest payments. These contracts effectively convert interest payments and principal repayment of this debt to U.S. dollars from euros, pounds sterling and Swiss francs and are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates as of December 31, 2020 and 2019, would have resulted in reductions in the fair values of our cross-currency swap contracts of approximately $250 million and $280 million, respectively.

Foreign-currency-sensitive financial instruments

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

As of December 31, 2020, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and a fair value of $4.8 billion and $5.4 billion, respectively. As of December 31, 2019, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and a fair value of $4.5 billion and $5.0 billion, respectively. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2020, would have resulted in an increase in fair value of this debt of $1.1 billion on this date and a reduction in income in the ensuing year of $1.0 billion. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2019, would have resulted in an increase in fair value of this debt of $1.0 billion on this date and a reduction in income in the ensuing year of $900 million. The impact on income from these hypothetical changes in foreign currency exchange rates would be substantially offset by the impact such changes would have on related cross-currency swap contracts, which are in place for the related foreign-currency-denominated debt.

We have cross-currency swap contracts that are designated as cash flow hedges of our debt denominated in euros, pounds sterling and Swiss francs with aggregate notional amounts of $4.8 billion as of both December 31, 2020 and 2019. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would have resulted in reductions in the fair values of these contracts of $1.1 billion and $1.0 billion on these dates, respectively. The impact of this hypothetical adverse movement in foreign currency exchange rates on ensuing years' income from these contracts would be fully offset by the corresponding hypothetical changes in the carrying amounts of the related hedged debt.

We enter into foreign currency forward and options contracts that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2020, the fair values of these contracts were a $28 million asset and a $237 million liability. As of December 31, 2019, the fair values of these contracts were a $223 million asset and a $31 million liability. As of December 31, 2020, we had primarily euro based open foreign currency forward contracts with notional amounts of $5.1 billion. As of December 31, 2019, we had primarily euro based open foreign currency forward contracts with notional amounts of $5.0 billion. With regard to foreign currency forward and option contracts that were open as of December 31, 2020, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2020, would have resulted in a reduction in fair value of these contracts of approximately $1.1 billion on this date and in the ensuing year, a reduction in income of approximately $420 million. With regard to contracts that were open as of December 31, 2019, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2019, would have resulted in a reduction in fair value of these contracts of $930 million on this date and in the ensuing year, a reduction in income of $400 million. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign-currency-sensitive instruments were designed to offset.

As of December 31, 2020 and 2019, we had open short-duration foreign currency forward contracts that mature in less than one month, with notional amounts of $1.0 billion and $1.2 billion, respectively, that hedged fluctuations of certain assets and liabilities denominated in foreign currencies but were not designated as hedges for accounting purposes. These contracts had no material net unrealized gains or losses as of December 31, 2020 and 2019. With regard to these foreign currency forward contracts that were open as of December 31, 2020 and 2019, a hypothetical 5% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would not have a material effect on the fair values of these contracts or related income in the respective ensuing years. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on assets and liabilities that these foreign-currency-sensitive instruments were designed to offset.

Market-price-sensitive financial instruments

As of December 31, 2020 and 2019, we were exposed to price risk on equity securities included in our portfolio of investments, which were acquired primarily for the promotion of business and strategic objectives. These investments are generally in small-capitalization stocks in the biotechnology industry. Price risk relative to our equity investment portfolio as of December 31, 2020 and 2019, was not material.

Counterparty credit risks

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

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

Item 9A. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under the Securities Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, Amgen's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2020.

Management determined that as of December 31, 2020, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

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

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our assessment, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

The effectiveness of the Company's internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing below, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2020.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited Amgen Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Amgen Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 and our report dated February 8, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Los Angeles, California
February 8, 2021

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about our Directors is incorporated by reference from the section entitled ITEM 1—ELECTION OF DIRECTORS in our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2020 (the Proxy Statement). Information about the procedures by which stockholders may recommend nominees for the Board of Directors is incorporated by reference from APPENDIX A—AMGEN INC. BOARD OF DIRECTORS GUIDELINES FOR DIRECTOR QUALIFICATIONS AND EVALUATIONS and OTHER MATTERS—Stockholder Proposals for the 2022 Annual Meeting in our Proxy Statement. Information about our Audit Committee, members of the committee and our Audit Committee financial experts is incorporated by reference from the section entitled CORPORATE GOVERNANCE—Audit Committee in our Proxy Statement. Information about our executive officers is contained in the discussion entitled Part I—Item 1. Business—Information about our Executive Officers.

Code of Ethics

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

Item 11. EXECUTIVE COMPENSATION

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

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

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table sets forth certain information as of December 31, 2020, concerning the shares of our common stock that may be issued under any form of award granted under our equity compensation plans in effect as of December 31, 2020 (including upon the exercise of options, upon the vesting of awards of restricted stock units (RSUs) or when performance units are earned and related dividend equivalents have been granted).

Plan category	(a) Number of securities to be issued upon exercise of outstanding options and rights	(b) Weighted-average exercise price of outstanding options and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by Amgen security holders:			
Amended and Restated 2009 Equity Incentive Plan[(1)]	9,890,702	$ 179.92	23,108,576
Amended and Restated 1991 Equity Incentive Plan[(2)]	5,913	—	—
Amended and Restated Employee Stock Purchase Plan	—	—	4,393,614
Total approved plans	9,896,615	179.92	27,502,190
Equity compensation plan not approved by Amgen security holders:			
Amgen Profit Sharing Plan for Employees in Ireland[(3)]	—	—	60,059
Total unapproved plans	—	—	60,059
Total all plans	9,896,615	$ 179.92	27,562,249

(1) The Amended and Restated 2009 Equity Incentive Plan employs a fungible share-counting formula for determining the number of shares available for issuance under the plan. In accordance with this formula, each option or stock appreciation right counts as one share, while each RSU, performance unit or dividend equivalent counts as 1.9 shares. The number under column (a) represents the actual number of shares issuable under our outstanding awards without giving effect to the fungible share-counting formula. The number under column (c) represents the number of shares available for issuance under this plan based on each such available share counting as one share. Commencing with the grants made in April 2012, RSUs and performance units accrue dividend equivalents that are payable in shares only to the extent and when the underlying RSUs vest or underlying performance units have been earned and the related shares are issued to the grantee. The performance units granted under this plan are earned based on the accomplishment of specified performance goals at the end of their respective three-year performance periods; the number of performance units granted represent target performance, and the maximum number of units that could be earned based on our performance is 200% of the performance units granted in 2018, 2019 and 2020.

As of December 31, 2020, the number of outstanding awards under column (a) includes (i) 4,721,305 shares issuable upon the exercise of outstanding options with a weighted-average exercise price of $179.92; (ii) 3,256,390 shares issuable upon the vesting of outstanding RSUs (including 199,676 related dividend equivalents); and (iii) 1,913,007 shares subject to outstanding 2018, 2019 and 2020 performance units (including 93,738 related dividend equivalents). The weighted-average exercise price shown in column (b) is for the outstanding options only. The number of available shares under column (c) represents the number of shares that remain available for future issuance under this plan as of December 31, 2020, employing the fungible share formula and presumes the issuance of target shares under the performance units granted in 2018, 2019 and 2020 and related dividend equivalents. The numbers under columns (a) and (c) do not give effect to the additional shares that could be issuable in the event above target performance on the performance goals under these outstanding performance units is achieved. Maximum performance under these goals could result in 200% of target shares being awarded for performance units granted in 2018, 2019 and 2020.

(2) This plan has terminated as to future grants. The number under column (a) with respect to this plan includes 5,913 shares issuable upon the settlement of deferred RSUs (including 1,160 related dividend equivalents).

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

Security Ownership of Directors and Executive Officers and Certain Beneficial Owners

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

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

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

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)1. Index to Financial Statements

The following Consolidated Financial Statements are included herein:

(a)2. Index to Financial Statement Schedules

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

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

(a)3. Exhibits

Exhibit No.	Description
2.1	Asset Purchase Agreement, dated August 25, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.2	Amendment No. 1 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on October 17, 2019 and incorporated herein by reference.)
2.3	Amendment No. 2 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.4	Letter Agreement, dated November 21, 2019, by and between Amgen Inc. and the parties named therein re: Treatment of Certain Product Inventory in connection with Amgen's acquisition of Otezla® (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.5	Irrevocable Guarantee, dated August 25, 2019, by and between Amgen Inc. and Bristol-Myers Squibb Company. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)

4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.6	Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.7	Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.8	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.9	Officers' Certificate of Amgen Inc., dated May 30, 2007, including form of the Company's 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
4.10	Officers' Certificate of Amgen Inc., dated May 23, 2008, including form of the Company's 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)
4.11	Officers' Certificate of Amgen Inc., dated January 16, 2009, including form of the Company's 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)
4.12	Officers' Certificate of Amgen Inc., dated March 12, 2010, including form of the Company's 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.)
4.13	Officers' Certificate of Amgen Inc., dated September 16, 2010, including form of the Company's 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)
4.14	Officers' Certificate of Amgen Inc., dated June 30, 2011, including form of the Company's 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)
4.15	Officers' Certificate of Amgen Inc., dated November 10, 2011, including form of the Company's 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)
4.16	Officers' Certificate of Amgen Inc., dated December 5, 2011, including form of the Company's 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)
4.17	Officers' Certificate of Amgen Inc., dated May 15, 2012, including forms of the Company's 3.625% Senior Notes due 2022 and 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)
4.18	Officers' Certificate of Amgen Inc., dated September 13, 2012, including form of the Company's 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)
4.19	Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
4.20	Officers' Certificate of Amgen Inc., dated May 22, 2014, including form of the Company's 3.625% Senior Notes due 2024. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)

4.21	Officer's Certificate of Amgen Inc., dated May 1, 2015, including forms of the Company's 2.700% Senior Notes due 2022, 3.125% Senior Notes due 2025 and 4.400% Senior Notes due 2045. (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.)
4.22	Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including forms of the Company's 1.250% Senior Notes due 2022 and 2.000% Senior Notes due 2026. (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.)
4.23	Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.24	Terms of the Bonds for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.25	Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.26	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of May 11, 2017 including form of the Company's 2.650% Senior Notes due 2022. (Filed as an exhibit to Form 8-K on May 11, 2017 and incorporated herein by reference.)
4.28	Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated by reference.)
4.29	Officer's Certificate of Amgen Inc., dated as of February 21, 2020, including forms of the Company's 1.900% Senior Notes due 2025, 2.200% Senior Notes due 2027, 2.450% Senior Notes due 2030, 3.150% Senior Notes due 2040 and 3.375% Senior Notes due 2050. (Filed as an exhibit to Form 8-K on February 21, 2020 and incorporated herein by reference.)
4.30	Officer's Certificate of Amgen Inc., dated as of May 6, 2020, including form of the Company's 2.300% Senior Notes due 2031. (Filed as an exhibit to Form 8-K on May 6, 2020 and incorporated herein by reference.)
4.31	Officer's Certificate of Amgen Inc., dated as of August 17, 2020, including forms of the Company's 2.770% Senior Notes due 2053. (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)
4.32	Registration Rights Agreement, dated as of August 17, 2020, by and among Amgen Inc., BofA Securities, Inc. and J.P. Morgan Securities LLC, as lead dealer managers, and BNP Paribas Securities Corp., Deutsche Bank Securities Inc., RBC Capital Markets, LLC, Blaylock Van, LLC and Siebert Williams Shank & Co., LLC, as co-dealer managers (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)
4.33*	Description of Amgen Inc.'s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1+	Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
10.2+	First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.)
10.3+	Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016 . (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)
10.4+*	Form of Grant of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 15, 2020.)
10.5+*	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 15, 2020.)

10.6+	Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.7+*	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on December 15, 2020.)
10.8+*	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended and Restated on October 21, 2020.)
10.9+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.10+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.11+	Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.12+	Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.13+	First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.14+	Second Amendment to the Amgen Inc. Supplemental Retirement Plan (As Amended and Restated effective October 23, 2019). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.15+	Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.)
10.16+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.17+	First Amendment to the Amgen Inc. Executive Incentive Plan, effective December 13, 2012. (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.)
10.18+	Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.19+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.20+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.21+	Second Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2020). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.22+	Agreement between Amgen Inc. and Murdo Gordon, dated July 25, 2018. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2018 on October 31, 2018 and incorporated herein by reference.)
10.23+	Agreement between Amgen Inc. and Peter Griffith, dated October 18, 2019. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)

10.24	Second Amended and Restated Credit Agreement, dated December 12, 2019, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent. (Filed as an exhibit to Form 8-K on December 12, 2019 and incorporated herein by reference.)
10.25	Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)
10.26	Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.27	Letter Agreement, dated June 25, 2019, by and between Amgen Inc. and UCB Celltech (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2019 on July 31, 2019 and incorporated herein by reference.)
10.28	Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)
10.29	Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.30	Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.31	Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.32	Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.33	Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
10.34	Side Letter Regarding Collaboration Agreement and Stivarga Agreement, dated February 13, 2020, by and between Onyx Pharmaceuticals, Inc. and Bayer HealthCare LLC. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)
10.35	Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.36	Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.37	Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.38	Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

10.39	Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.40	Amendment No. 1 to the Collaboration Agreement, dated March 20, 2018, by and between Novartis Pharma AG and Amgen Inc . (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.)
10.41	Amendment No. 2 to the Collaboration Agreement, dated August 19, 2020, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2020 on October 29, 2020 and incorporated herein by reference.)
10.42	Collaboration Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene Switzerland GmbH, a wholly-owned subsidiary of BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.43	Guarantee, dated as of October 31, 2019, made by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.44	Share Purchase Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.45	Amendment No. 1 to Share Purchase Agreement, dated December 6, 2019, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.46	Restated Amendment No. 2 to Share Purchase Agreement, dated September 24, 2020, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2020 on October 29, 2020 and incorporated herein by reference.)
10.47	Collaboration Agreement dated March 30, 2012 by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, a wholly owned subsidiary of AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2012 on May 8, 2012 and incorporated herein by reference.)
10.48	Amendment No. 1 to the Collaboration Agreement, dated October 1, 2014, by and among Amgen Inc., AstraZeneca Collaboration Ventures, LLC and AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2014 on February 19, 2015 and incorporated herein by reference.)
10.49	Amendment Nos. 2 through 6 to the March 30, 2012 Collaboration Agreement between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, dated May 2 and 27 and October 2, 2016, January 31, 2018, and May 15, 2020, respectively (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2020 on July 29, 2020 and incorporated herein by reference.)
10.50*	Amendment No. 7 to the Collaboration Agreement, dated December 18, 2020, by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.)
21*	Subsidiaries of the Company.
23	Consent of the Independent Registered Public Accounting Firm. The consent is set forth on page 94 of this Annual Report on the 10-K.
24	Power of Attorney. The Power of Attorney is set forth on page 95 of this Annual Report on Form 10-K.
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.

101.INS	Inline XBRL Instance Document - the instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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

Item 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

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

AMGEN INC.
(Registrant)

Date: February 8, 2021

By: /S/ PETER H. GRIFFITH

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

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

of our reports dated February 8, 2021, with respect to the consolidated financial statements of Amgen Inc. and the effectiveness of internal control over financial reporting of Amgen Inc. included in this Annual Report (Form 10-K) of Amgen Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Los Angeles, California
February 8, 2021

EXHIBIT 24

POWER OF ATTORNEY

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

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

Signature	Title	Date
/S/ ROBERT A. BRADWAY **Robert A. Bradway**	Chairman of the Board, Chief Executive Officer and President, and Director (Principal Executive Officer)	2/8/2021
/S/ PETER H. GRIFFITH **Peter H. Griffith**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	2/8/2021
/S/ LINDA H. LOUIE **Linda H. Louie**	Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)	2/8/2021
/S/ WANDA M. AUSTIN **Wanda M. Austin**	Director	2/8/2021
/S/ BRIAN J. DRUKER **Brian J. Druker**	Director	2/8/2021
/S/ ROBERT A. ECKERT **Robert A. Eckert**	Director	2/8/2021
/S/ GREG C. GARLAND **Greg C. Garland**	Director	2/8/2021
/S/ FRED HASSAN **Fred Hassan**	Director	2/8/2021
/S/ CHARLES M. HOLLEY, JR. **Charles M. Holley, Jr.**	Director	2/8/2021
/S/ TYLER JACKS **Tyler Jacks**	Director	2/8/2021
/S/ ELLEN J. KULLMAN **Ellen J. Kullman**	Director	2/8/2021
/S/ AMY E. MILES **Amy E. Miles**	Director	2/8/2021
/S/ RONALD D. SUGAR **Ronald D. Sugar**	Director	2/8/2021
/S/ R. SANDERS WILLIAMS **R. Sanders Williams**	Director	2/8/2021

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amgen Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 8, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matters

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

Sales deductions

Description of the Matter

As of December 31, 2020, the Company recorded accrued sales deductions of $4.8 billion. As described in Note 1 to the financial statements under the caption "Product sales and sales deductions," revenues from product sales are recognized net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively sales deductions), which are established at the time of sale.

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

How We Addressed the Matter in Our Audit

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

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

Unrecognized tax benefits

Description of the Matter

As discussed in Notes 1 and 6 to the consolidated financial statements, the Company operates in various jurisdictions in which differing interpretations of complex tax laws and regulations create uncertainty and necessitate the use of significant judgment in the determination of the Company's unrecognized tax benefits related to allocation of profits among various jurisdictions ("transfer pricing"), particularly in the U.S. federal tax jurisdiction where the Company has significant assets and operations. In this regard, the Company uses significant judgment in (1) determining whether a tax position's technical merits are more-likely-than-not to be sustained and (2) measuring the amount of tax benefit that qualifies for recognition. As of December 31, 2020, the Company accrued $3.4 billion of gross unrecognized tax benefits including transfer pricing. Auditing the assessment of the technical merits and measurement of the Company's unrecognized tax benefits is challenging because they can be complex, highly judgmental, and based on interpretations of tax laws and regulations and application of those interpretations to the Company's facts and circumstances.

How We Addressed the Matter in Our Audit

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1980.
Los Angeles, California
February 8, 2021

AMGEN INC.

CONSOLIDATED STATEMENTS OF INCOME

Years ended December 31, 2020, 2019 and 2018

(In millions, except per-share data)

	2020	2019	2018
Revenues:			
Product sales	$ 24,240	$ 22,204	$ 22,533
Other revenues	1,184	1,158	1,214
Total revenues	25,424	23,362	23,747
Operating expenses:			
Cost of sales	6,159	4,356	4,101
Research and development	4,207	4,116	3,737
Selling, general and administrative	5,730	5,150	5,332
Other	189	66	314
Total operating expenses	16,285	13,688	13,484
Operating income	9,139	9,674	10,263
Interest expense, net	1,262	1,289	1,392
Interest and other income, net	256	753	674
Income before income taxes	8,133	9,138	9,545
Provision for income taxes	869	1,296	1,151
Net income	$ 7,264	$ 7,842	$ 8,394
Earnings per share:			
Basic	$ 12.40	$ 12.96	$ 12.70
Diluted	$ 12.31	$ 12.88	$ 12.62
Shares used in the calculation of earnings per share:			
Basic	586	605	661
Diluted	590	609	665

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Years ended December 31, 2020, 2019 and 2018

(In millions)

	2020	2019	2018
Net income	$ 7,264	$ 7,842	$ 8,394
Other comprehensive (loss) income, net of reclassification adjustments and taxes:			
Gains (losses) on foreign currency translation	9	(48)	(141)
(Losses) gains on cash flow hedges	(438)	(66)	247
(Losses) gains on available-for-sale securities	(21)	360	(185)
Other losses	(7)	(5)	(2)
Other comprehensive (loss) income, net of taxes	(457)	241	(81)
Comprehensive income	$ 6,807	$ 8,083	$ 8,313

See accompanying notes.

AMGEN INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2020 and 2019

(In millions, except per-share data)

	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,266	$ 6,037
Marketable securities	4,381	2,874
Trade receivables, net	4,525	4,057
Inventories	3,893	3,584
Other current assets	2,079	1,888
Total current assets	21,144	18,440
Property, plant and equipment, net	4,889	4,928
Intangible assets, net	16,587	19,413
Goodwill	14,689	14,703
Other assets	5,639	2,223
Total assets	$ 62,948	$ 59,707
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,421	$ 1,371
Accrued liabilities	10,141	8,511
Current portion of long-term debt	91	2,953
Total current liabilities	11,653	12,835
Long-term debt	32,895	26,950
Long-term tax liabilities	6,968	8,037
Other noncurrent liabilities	2,023	2,212
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value per share; 2,750.0 shares authorized; outstanding — 578.3 shares in 2020 and 591.4 shares in 2019	31,802	31,531
Accumulated deficit	(21,408)	(21,330)
Accumulated other comprehensive loss	(985)	(528)
Total stockholders' equity	9,409	9,673
Total liabilities and stockholders' equity	$ 62,948	$ 59,707

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended December 31, 2020, 2019 and 2018

(In millions, except per-share data)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total
Balance as of December 31, 2017	722.2	$ 30,992	$ (5,072)	$ (679)	$ 25,241
Cumulative effect of changes in accounting principles, net of taxes	—	—	38	(9)	29
Net income	—	—	8,394	—	8,394
Other comprehensive loss, net of taxes	—	—	—	(81)	(81)
Dividends declared on common stock ($5.41 per share)	—	—	(3,482)	—	(3,482)
Issuance of common stock in connection with the Company's equity award programs	1.9	56	—	—	56
Stock-based compensation expense	—	327	—	—	327
Tax impact related to employee stock-based compensation expense	—	(129)	—	—	(129)
Repurchases of common stock	(94.5)	—	(17,855)	—	(17,855)
Balance as of December 31, 2018	629.6	31,246	(17,977)	(769)	12,500
Net income	—	—	7,842	—	7,842
Other comprehensive income, net of taxes	—	—	—	241	241
Dividends declared on common stock ($5.95 per share)	—	—	(3,555)	—	(3,555)
Issuance of common stock in connection with the Company's equity award programs	2.0	97	—	—	97
Stock-based compensation expense	—	323	—	—	323
Tax impact related to employee stock-based compensation expense	—	(135)	—	—	(135)
Repurchases of common stock	(40.2)	—	(7,640)	—	(7,640)
Balance as of December 31, 2019	591.4	31,531	(21,330)	(528)	9,673
Cumulative effect of changes in accounting principles, net of taxes	—	—	(2)	—	(2)
Net income	—	—	7,264	—	7,264
Other comprehensive loss, net of taxes	—	—	—	(457)	(457)
Dividends declared on common stock ($6.56 per share)	—	—	(3,843)	—	(3,843)
Issuance of common stock in connection with the Company's equity award programs	2.1	91	—	—	91
Stock-based compensation expense	—	349	—	—	349
Tax impact related to employee stock-based compensation expense	—	(169)	—	—	(169)
Repurchases of common stock	(15.2)	—	(3,497)	—	(3,497)
Balance as of December 31, 2020	578.3	$ 31,802	$ (21,408)	$ (985)	$ 9,409

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2020, 2019 and 2018

(In millions)

	2020	2019	2018
Cash flows from operating activities:			
Net income	$ 7,264	$ 7,842	$ 8,394
Depreciation, amortization and other	3,601	2,206	1,946
Stock-based compensation expense	330	308	311
Deferred income taxes	(287)	(289)	(363)
Other items, net	(195)	(186)	386
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	(427)	(504)	(378)
Inventories	(215)	(66)	(3)
Other assets	129	10	35
Accounts payable	45	164	(143)
Accrued income taxes, net	(249)	(585)	(361)
Long-term tax liabilities	(482)	(146)	258
Other liabilities	983	396	1,214
Net cash provided by operating activities	10,497	9,150	11,296
Cash flows from investing activities:			
Purchases of marketable securities	(8,477)	(9,394)	(18,741)
Proceeds from sales of marketable securities	2,597	8,842	28,356
Proceeds from maturities of marketable securities	4,381	20,548	5,412
Purchases of property, plant and equipment	(608)	(618)	(738)
Cash paid for acquisitions, net of cash acquired	—	(13,617)	195
Purchases of equity method investments	(3,219)	(24)	(40)
Other	(75)	(28)	(105)
Net cash (used in) provided by investing activities	(5,401)	5,709	14,339
Cash flows from financing activities:			
Net proceeds from issuance of debt	8,914	—	—
Repayment of debt	(6,450)	(4,514)	(1,121)
Repurchases of common stock	(3,486)	(7,702)	(17,794)
Dividends paid	(3,755)	(3,509)	(3,507)
Other	(90)	(42)	(68)
Net cash used in financing activities	(4,867)	(15,767)	(22,490)
Increase (decrease) in cash and cash equivalents	229	(908)	3,145
Cash and cash equivalents at beginning of year	6,037	6,945	3,800
Cash and cash equivalents at end of year	$ 6,266	$ 6,037	$ 6,945

See accompanying notes.

1. Summary of significant accounting policies

Business

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

Principles of consolidation

The consolidated financial statements include the accounts of Amgen as well as its majority-owned subsidiaries. We do not have any significant interests in any variable interest entities. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Revenues

Product sales and sales deductions

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

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that an adjustment is appropriate. Accruals are also adjusted to reflect actual results. Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given period, can be affected by the mix of products sold. Included in sales deductions are immaterial net adjustments related to prior-period sales due to changes in estimates. Historically, such amounts have represented less than 1% of the aggregate sales deductions charged against product sales.

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

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

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

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

Other revenues

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

Arrangements with multiple-performance obligations

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

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

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

Research and development costs

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

Selling, general and administrative costs

SG&A costs are primarily composed of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses; the U.S. healthcare reform federal excise fee on Branded Prescription Pharmaceutical Manufacturers and Importers; and other general and administrative costs. Advertising costs are expensed as incurred and were $962 million, $789 million and $674 million during the years ended December 31, 2020, 2019 and 2018, respectively. SG&A expenses also include costs and cost recoveries associated with marketing and promotion efforts under certain collaborative arrangements. Net payment or reimbursement of SG&A costs is recognized when the obligations are incurred or we become entitled to the cost recovery. See Note 8, Collaborations.

Leases

Adoption of new lease standard

In February 2016, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the accounting and disclosure of leases. This new standard requires that lessees recognize the assets and liabilities that arise from leases on the balance sheet, including leases classified as operating leases, and that they disclose qualitative and quantitative information about leasing arrangements. The FASB subsequently issued additional amendments to address issues arising from the implementation of the new lease standard. We adopted this standard as of January 1, 2019, using the modified-retrospective method, which provides a method for recording existing leases at adoption. We used the adoption date as our date of initial application, and thus, comparative-period financial information is not presented for periods prior to the adoption date. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed us to carry forward the historical lease classification.

Adoption of the new standard resulted in total lease liabilities of $510 million and right-of-use (ROU) assets of $439 million as of January 1, 2019. The difference between the initial lease liabilities and the ROU assets is primarily related to previously existing lease liabilities. The standard did not materially impact our Consolidated Statements of Income and had no impact on our Consolidated Statements of Cash Flows. Our accounting policies under the new standard are described below. See Note 13, Leases.

Lease recognition

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

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

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

Stock-based compensation

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

Income taxes

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

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

Acquisitions

We first determine whether a set of assets acquired constitute a business and should be accounted for as a business combination. If the assets acquired are not a business, we account for the transaction as an asset acquisition. Business combinations are accounted for by using the acquisition method of accounting. Under the acquisition method, assets acquired, including in-process research and development (IPR&D) projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with a business combination (including the assumption of an acquiree's liability arising from an acquisition it consummated prior to our acquisition) are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in earnings. In contrast, asset acquisitions are accounted for using a cost accumulation and allocation model. Under this model, the cost of the acquisition is allocated to the assets acquired and liabilities assumed. Contingent consideration obligations incurred in connection with an asset acquisition are recorded when it is probable that they will occur and they can be reasonably estimated. See Note 2, Acquisitions, and Note 17, Fair value measurement.

Cash equivalents

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

Interest-bearing securities

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

Inventories

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

Derivatives

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

Property, plant and equipment, net

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

Goodwill and other intangible assets

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

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

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

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

Contingencies

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

Foreign currency translation

The net assets of international subsidiaries whose local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating net assets of these subsidiaries at changing rates are recognized in AOCI. The subsidiaries' earnings are translated into U.S. dollars using average exchange rates.

Equity method investments

The equity method of accounting is used for equity investments that give us the ability to exert significant influence, but not control, over an investee based on such factors as our ownership percentage, voting and other shareholder rights, board of director representation and the existence of other collaborative or business relationships. The equity method of accounting requires us to allocate the difference between the fair value of securities acquired and our proportionate share of the carrying value of the underlying assets (the basis difference) to various items and amortize such differences over their useful lives. Our share of the investees' earnings or losses and amortization of basis differences, if any, are recorded one quarter in arrears in Interest and other income, net, in the Consolidated Statements of Income.

We record impairment losses on our equity method investments if we deem the impairment to be other-than-temporary. We deem an impairment to be other-than-temporary based on various factors, including but not limited to, the length of time the fair value is below the carrying value, volatility of the security price and our intent and ability to retain the investment to allow for a recovery in fair value.

Recent accounting pronouncements

In June 2016, the FASB issued a new accounting standard that amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the incurred-loss model with an expected-loss model. Accordingly, these financial assets are now presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the former other-than-temporary-impairment model. We adopted this standard as of January 1, 2020, using a modified-retrospective approach. Adoption of the standard did not have a material impact on our consolidated financial statements.

In March 2020, the FASB issued a new accounting standard to ease the financial reporting burdens of the expected market transition from the London Interbank Offered Rate (LIBOR) and other interbank offered rates to alternative reference rates, commonly referred to as reference rate reform. The new standard provides temporary optional expedients and exceptions to current GAAP guidance on contract modifications and hedge accounting. Specifically, a modification to transition to an alternative reference rate is treated as an event that does not require contract remeasurement or reassessment of a previous accounting treatment. Moreover, for all types of hedging relationships, an entity may change the reference rate without having to dedesignate the hedging relationship. The standard is generally effective for all contract modifications made and hedging relationships evaluated through December 31, 2022. In January 2021, the FASB issued a new accounting standard to expand on the scope of the original March 2020 standard to include derivative instruments on discounting transactions. We are currently evaluating the impact that both standards will have on our consolidated financial statements.

2. Acquisitions

Otezla® (apremilast)

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

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

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

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

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

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

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

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

Nuevolution AB

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

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

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

Kirin-Amgen, Inc.

During the first quarter of 2018, we acquired the remaining 50% ownership of Kirin-Amgen, Inc. (K-A), from Kirin Holdings Company, Limited (Kirin), making K-A a wholly owned subsidiary of Amgen. Upon the acquisition, K-A's operations have been included in our consolidated financial statements commencing on the share acquisition date. The acquisition relieved Amgen of future royalty obligations to K-A.

Prior to the share acquisition date, we owned 50% of K-A and accounted for our interest in K-A by using the equity method of accounting.

The transaction was accounted for as a step acquisition of a business in which we were required to remeasure our existing 50% ownership interest at fair value. In addition, we were required to effectively settle our preexisting relationship with K-A, which resulted in a loss. Together the gain on the remeasurement of our existing ownership interest and the loss from the settlement of the preexisting relationship resulted in a net gain of $80 million, which was recorded in Interest and other income, net, in the Consolidated Statements of Income.

The primary means of consideration for this transaction was a payment of $780 million in cash. The aggregate share acquisition date consideration to acquire the remaining 50% ownership in K-A and the fair value of Amgen's preacquisition investment consisted of the following (in millions):

	Amounts
Total cash paid to Kirin	$ 780
Fair value of contingent consideration obligation	45
Loss on settlement of preexisting relationship	(168)
Total consideration transferred to acquire K-A	657
Fair value of Amgen's investment in K-A	825
Total acquisition date fair value	$ 1,482

In connection with this acquisition, we are obligated to make single-digit royalty payments to Kirin contingent upon sales of brodalumab. The estimated fair value of this contingent consideration obligation was $45 million as of the share acquisition date.

The fair values of assets acquired and liabilities assumed consisted of cash of $977 million, licensing rights of $470 million, deferred tax liabilities of $102 million, other assets and liabilities of $131 million and goodwill of $6 million. The estimated fair value of acquired licensing rights was determined by using a probability-related-income approach, which is based on the present value of the incremental after-tax cash flows attributable only to the intangible asset. The projected cash flows were based on certain assumptions, including estimates of future revenues and expenses and the time and resources needed to maintain the assets through commercialization. The licensing rights will be amortized over a weighted-average period of four years by using the straight-line method. The excess of the share acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $6 million was recorded as goodwill, which is not deductible for tax purposes. The $131 million in other assets and liabilities primarily represents receivables for royalties earned by K-A but not yet received, partially offset by payables representing R&D expenses incurred but not yet reimbursed by K-A.

Pro forma results of operations for this acquisition have not been presented because this acquisition was not material to our consolidated results of operations.

3. Revenues

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

Revenues were as follows (in millions):

	Year ended December 31, 2020			Year ended December 31, 2019			Year ended December 31, 2018		
	U.S.	ROW	Total	U.S.	ROW	Total	U.S.	ROW	Total
Enbrel® (etanercept)	$ 4,855	$ 141	$ 4,996	$ 5,050	$ 176	$ 5,226	$ 4,807	$ 207	$ 5,014
Prolia® (denosumab)	1,830	933	2,763	1,772	900	2,672	1,500	791	2,291
Neulasta® (pegfilgrastim)	2,001	292	2,293	2,814	407	3,221	3,866	609	4,475
Otezla®(1)	1,790	405	2,195	139	39	178	—	—	—
XGEVA® (denosumab)	1,405	494	1,899	1,457	478	1,935	1,338	448	1,786
Aranesp® (darbepoetin alfa)	629	939	1,568	758	971	1,729	942	935	1,877
KYPROLIS® (carfilzomib)	710	355	1,065	654	390	1,044	583	385	968
Repatha® (evolocumab)	459	428	887	376	285	661	358	192	550
Other products	4,306	2,268	6,574	3,511	2,027	5,538	4,035	1,537	5,572
Total product sales(2)	17,985	6,255	24,240	16,531	5,673	22,204	17,429	5,104	22,533
Other revenues	511	673	1,184	693	465	1,158	929	285	1,214
Total revenues	$ 18,496	$ 6,928	$ 25,424	$ 17,224	$ 6,138	$ 23,362	$ 18,358	$ 5,389	$ 23,747

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

(2) Hedging gains and losses, which are included in product sales, were not material for the years ended December 31, 2020, 2019 and 2018.

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

We had product sales to three customers, each of them accounting for more than 10% of total revenues for each of the years ended December 31, 2020, 2019 and 2018. For the year ended December 31, 2020, on a combined basis, these customers accounted for 83% of total gross revenues as shown in the following table. Certain information with respect to these customers was as follows (dollar amounts in millions):

	Years ended December 31,		
	2020	2019	2018
AmerisourceBergen Corporation:			
Gross product sales	$ 14,743	$ 12,301	$ 12,091
% of total gross revenues	34 %	33 %	33 %
McKesson Corporation:			
Gross product sales	$ 13,779	$ 11,795	$ 11,434
% of total gross revenues	32 %	31 %	31 %
Cardinal Health, Inc.:			
Gross product sales	$ 7,332	$ 6,538	$ 7,475
% of total gross revenues	17 %	17 %	20 %

As of December 31, 2020 and 2019, amounts due from these three customers each exceeded 10% of gross trade receivables and accounted for 74% and 73%, respectively, of net trade receivables on a combined basis. As of December 31, 2020 and 2019, 28% and 27%, respectively, of net trade receivables were due from customers located outside the United States, the majority of which were from Europe. Our total allowance for doubtful accounts as of December 31, 2020 and 2019, was not material.

4. Stock-based compensation

Our Amended and Restated 2009 Equity Incentive Plan (the Amended 2009 Plan) authorizes for issuance to employees of Amgen and nonemployee members of our Board of Directors shares of our common stock pursuant to grants of equity-based awards, including RSUs, stock options and performance units. The pool of shares available under the Amended 2009 Plan is reduced by one share for each stock option granted and by 1.9 shares for other types of awards granted, including RSUs and performance units (full-value awards). In general, if any shares subject to an award granted under the Amended 2009 Plan expire or become forfeited, terminated or canceled without the issuance of shares, the shares subject to such awards are added back into the authorized pool on the same basis that they were removed. In addition, under the Amended 2009 Plan, shares withheld to pay for minimum statutory tax obligations with respect to full-value awards are added back into the authorized pool on the basis of 1.9 shares. As of December 31, 2020, the Amended 2009 Plan provides for future grants and/or issuances of up to approximately 23 million shares of our common stock. Stock-based awards under our employee compensation plans are made with newly issued shares reserved for this purpose.

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

	Years ended December 31,		
	2020	2019	2018
RSUs	$ 178	$ 168	$ 165
Performance units	118	105	117
Stock options	34	35	29
Total stock-based compensation expense, pretax	330	308	311
Tax benefit from stock-based compensation expense	(72)	(67)	(67)
Total stock-based compensation expense, net of tax	$ 258	$ 241	$ 244

Restricted stock units and stock options

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

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

Restricted stock units

The grant date fair value of an RSU equals the closing price of our common stock on the grant date, as RSUs accrue dividend equivalents during their vesting period. The weighted-average grant date fair values per unit of RSUs granted during the years ended December 31, 2020, 2019 and 2018, were $235.63, $182.12 and $179.18, respectively.

The following table summarizes information regarding our RSUs:

	Year ended December 31, 2020	
	Units (in millions)	Weighted-average grant date fair value
Balance nonvested as of December 31, 2019	3.1	$ 174.97
Granted	1.1	$ 235.63
Vested	(1.0)	$ 167.23
Forfeited	(0.2)	$ 190.15
Balance nonvested as of December 31, 2020	3.0	$ 198.11

The total grant date fair values of RSUs that vested during the years ended December 31, 2020, 2019 and 2018, were $161 million, $160 million and $167 million, respectively.

Stock options

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

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

	Years ended December 31,		
	2020	2019	2018
Closing price of our common stock on grant date	$ 236.36	$ 177.31	$ 177.46
Expected volatility (average of implied and historical volatility)	28.1 %	23.5 %	24.6 %
Expected life (in years)	5.8	5.8	5.8
Risk-free interest rate	0.4 %	2.4 %	2.8 %
Expected dividend yield	3.0 %	3.1 %	2.9 %
Fair value of stock options granted	$ 42.34	$ 30.47	$ 34.60

The following table summarizes information regarding our stock options:

	Year ended December 31, 2020			
	Options (in millions)	Weighted-average exercise price	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in millions)
Balance unexercised as of December 31, 2019	4.8	$ 157.00		
Granted	1.0	$ 236.36		
Exercised	(0.9)	$ 117.90		
Expired/forfeited	(0.2)	$ 178.36		
Balance unexercised as of December 31, 2020	4.7	$ 179.90	7.3	$ 243
Vested or expected to vest as of December 31, 2020	4.5	$ 178.37	7.3	$ 239
Exercisable as of December 31, 2020	1.5	$ 150.80	5.5	$ 120

The total intrinsic values of options exercised during the years ended December 31, 2020, 2019 and 2018, were $98 million, $68 million and $53 million, respectively. The actual tax benefits realized from tax deductions from option exercises during the years ended December 31, 2020, 2019 and 2018, were $21 million, $15 million and $12 million, respectively.

As of December 31, 2020, $345 million of unrecognized compensation cost was related to nonvested RSUs and unvested stock options, which is expected to be recognized over a weighted-average period of 1.8 years.

Performance units

Certain management-level employees also receive annual grants of performance units, which give the recipient the right to receive common stock that is contingent upon achievement of specified preestablished goals over the performance period, which is generally three years. The performance goals for the units granted during the years ended December 31, 2020, 2019 and 2018, which are accounted for as equity awards, are based on (i) Amgen's stockholder return compared with a comparator group of companies, which are considered market conditions and are therefore reflected in the grant date fair values of the units, and (ii) Amgen's stand-alone financial performance measures, which are considered performance conditions. The expense recognized for awards is based on the grant date fair value of a unit multiplied by the number of units expected to be earned with respect to the related performance conditions, net of estimated forfeitures. Depending on the outcome of these performance goals, a recipient may ultimately earn a number of units greater or less than the number of units granted. Shares of our common stock are issued on a one-for-one basis for each performance unit earned. In general, performance unit awards vest at the end of the performance period. The performance award program provides for accelerated or continued vesting in certain circumstances as defined in the plan, including upon death, disability, a change in control and retirement of employees who meet certain service and/or age requirements. Performance units accrue dividend equivalents that are typically payable in shares only when and to the extent the underlying performance units vest and are issued to the recipient, including with respect to market and performance conditions that affect the number of performance units earned.

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

	Years ended December 31,		
	2020	2019	2018
Closing price of our common stock on grant date	$ 236.36	$ 177.31	$ 177.93
Volatility	27.5 %	22.1 %	23.8 %
Risk-free interest rate	0.2 %	2.3 %	2.6 %
Fair value of units granted	$ 249.07	$ 188.40	$ 189.21

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

As of December 31, 2020 and 2019, 1.8 million and 2.0 million performance units were outstanding with weighted-average grant date fair values per unit of $207.52 and $185.64 per unit, respectively. During the year ended December 31, 2020, 0.6 million performance units with a weighted-average grant date fair value per unit of $249.07 were granted, and 0.1 million performance units with a weighted-average grant date fair value per unit of $199.86 were forfeited.

The total fair values of performance units paid during the years ended December 31, 2020, 2019 and 2018 were $230 million, $176 million and $133 million, respectively, based on the number of performance units earned multiplied by the closing stock price of our common stock on the last day of the performance period.

As of December 31, 2020, $127 million of unrecognized compensation cost was related to nonvested performance units, which is expected to be recognized over a weighted-average period of one year.

5. Defined contribution plan

The Company has defined contribution plans to which certain employees of the Company and participating subsidiaries may defer compensation for income tax purposes. Participants are eligible to receive matching contributions based on their contributions, in addition to other Company contributions. Defined contribution plan expenses were $231 million, $220 million and $173 million for the years ended December 31, 2020, 2019 and 2018, respectively.

6. Income taxes

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

	Years ended December 31,		
	2020	2019	2018
Domestic	$ 4,087	$ 4,371	$ 4,856
Foreign	4,046	4,767	4,689
Total income before income taxes	$ 8,133	$ 9,138	$ 9,545

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

	Years ended December 31,		
	2020	2019	2018
Current provision:			
Federal	$ 921	$ 1,284	$ 1,270
State	34	39	17
Foreign	277	277	227
Total current provision	1,232	1,600	1,514
Deferred (benefit) provision:			
Federal	(321)	(276)	(317)
State	9	(22)	(7)
Foreign	(51)	(6)	(39)
Total deferred benefit	(363)	(304)	(363)
Total provision for income taxes	$ 869	$ 1,296	$ 1,151

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

	December 31,	
	2020	2019
Deferred income tax assets:		
NOL and credit carryforwards	$ 794	$ 800
Accrued expenses	561	457
Expenses capitalized for tax	144	170
Stock-based compensation	92	91
Other	301	269
Total deferred income tax assets	1,892	1,787
Valuation allowance	(571)	(517)
Net deferred income tax assets	1,321	1,270
Deferred income tax liabilities:		
Acquired intangible assets	(903)	(1,288)
Debt	(282)	(210)
Fixed assets	(148)	(53)
Other	(189)	(233)
Total deferred income tax liabilities	(1,522)	(1,784)
Total deferred income taxes, net	$ (201)	$ (514)

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

The valuation allowance increased in 2020, primarily driven by the Company's expectation that some state R&D credits will not be utilized and that certain foreign net operating losses will expire unused.

As of December 31, 2020, we had $20 million of federal tax credit carryforwards available to reduce future federal income taxes and have provided no valuation allowance for those federal tax credit carryforwards. The federal tax credit carryforwards expire between 2023 and 2035. We had $681 million of state tax credit carryforwards available to reduce future state income taxes and have provided a valuation allowance for $585 million of those state tax credit carryforwards.

As of December 31, 2020, we had $143 million of federal NOL carryforwards available to reduce future federal income taxes and have provided a valuation allowance for $6 million of those federal NOL carryforwards. The federal NOL carryforwards, for which no valuation allowance has been provided, expire between 2021 and 2035. We had $167 million of state NOL carryforwards available to reduce future state income taxes and have provided a valuation allowance for all of the state NOL carryforwards. We had $1.9 billion of foreign NOL carryforwards available to reduce future foreign income taxes and have provided a valuation allowance for $754 million of those foreign NOL carryforwards. For the foreign NOLs with no valuation allowance provided, $861 million has no expiry; and the remainder will expire between 2021 and 2030.

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

	Years ended December 31,		
	2020	2019	2018
Beginning balance	$ 3,287	$ 3,061	$ 2,953
Additions based on tax positions related to the current year	165	215	173
Additions based on tax positions related to prior years	3	22	13
Reductions for tax positions of prior years	(35)	(11)	(17)
Settlements	(68)	—	(61)
Ending balance	$ 3,352	$ 3,287	$ 3,061

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

Interest and penalties related to UTBs are included in our provision for income taxes. During the years ended December 31, 2020, 2019 and 2018, we recognized $116 million, $198 million and $137 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. The decrease in interest expense for the year ended December 31, 2020 was primarily due to lower interest rates during 2020. As of December 31, 2020 and 2019, accrued interest and penalties associated with UTBs were $783 million and $667 million, respectively.

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

	Years ended December 31,		
	2020	2019	2018
Federal statutory tax rate	21.0 %	21.0 %	21.0 %
Foreign earnings	(4.7)%	(4.5)%	(4.3)%
Foreign-derived intangible income	(0.7)%	(0.7)%	(0.4)%
Credits, Puerto Rico Excise Tax	(2.9)%	(2.6)%	(2.5)%
2017 Tax Act, net impact on intercompany sales	— %	— %	(1.8)%
Interest on uncertain tax positions	1.1 %	1.6 %	1.2 %
Credits, primarily federal R&D	(1.4)%	(1.0)%	(0.8)%
Audit settlements	(1.0)%	— %	(0.3)%
Other, net	(0.7)%	0.4 %	— %
Effective tax rate	10.7 %	14.2 %	12.1 %

The effective tax rates for the years ended December 31, 2020, 2019 and 2018 differ from the federal statutory rate primarily due to impacts of the jurisdictional mix of income and expenses. Substantially all of the benefit to our effective tax rate from foreign earnings results from the Company's operations in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes. Our operations in Puerto Rico are subject to tax incentive grants through 2035. Additionally, the Company's operations conducted in Singapore are subject to a tax incentive grant through 2034. Our foreign earnings are also subject to U.S. tax at a reduced rate of 10.5%.

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

Income taxes paid during the years ended December 31, 2020, 2019 and 2018, were $1.4 billion, $1.9 billion and $1.9 billion, respectively.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes may arise with tax authorities involving issues regarding the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and relevant facts. In 2017, we received a Revenue Agent Report (RAR) and a modified RAR from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012 proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. However, we have been unable to reach resolution at the administrative appeals level, and we anticipate that we will receive a Notice of Deficiency, which we would expect to vigorously contest through the judicial process. In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagree with the 2013, 2014 and 2015 proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. The IRS audit for years 2016, 2017 and 2018 is expected to start in the near term. We are also currently under examination by a number of other state and foreign tax jurisdictions.

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

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

7. Earnings per share

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

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

	Years ended December 31,		
	2020	2019	2018
Income (Numerator):			
Net income for basic and diluted EPS	$ 7,264	$ 7,842	$ 8,394
Shares (Denominator):			
Weighted-average shares for basic EPS	586	605	661
Effect of dilutive securities	4	4	4
Weighted-average shares for diluted EPS	590	609	665
Basic EPS	$ 12.40	$ 12.96	$ 12.70
Diluted EPS	$ 12.31	$ 12.88	$ 12.62

For each of the three years ended December 31, 2020, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

8. Collaborations

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

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

BeiGene, Ltd.

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

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

During the year ended December 31, 2020, net costs recovered from BeiGene for oncology product candidates were $225 million and were recorded as an offset to R&D expense in the Consolidated Statements of Income. Profit share payments and product sales between Amgen and BeiGene were not material for the year ended December 31, 2020. As of December 31, 2020, the amount owed from BeiGene for net costs recovered was $113 million, which is included in Other current assets in the Consolidated Balance Sheets. In connection with this collaboration, we acquired an ownership interest in BeiGene. See Note 9, Investments.

Novartis Pharma AG

We are in a collaboration with Novartis Pharma AG (Novartis) to jointly develop and commercialize Aimovig® (erenumab-aooe). In the United States, Amgen and Novartis jointly develop and collaborate on the commercialization of Aimovig®. Amgen, as the principal, recognizes product sales of Aimovig® in the United States, shares U.S. commercialization costs with Novartis and pays Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig®. Novartis pays Amgen double-digit royalties on net sales of the product in the Novartis exclusive territories and funds a portion of global R&D expenses. In addition, Novartis will make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds are achieved with respect to Aimovig® in the United States. Amgen manufactures and supplies Aimovig® worldwide. The migraine collaboration will continue for the commercial life of the product unless terminated in accordance with its terms.

We are currently involved in litigation with Novartis over our collaboration agreements for the development and commercialization of Aimovig®. See Note 19, Contingencies and commitments.

During the years ended December 31, 2020 and 2019, net costs recovered from Novartis for migraine products were $192 million and $187 million, respectively, and were recorded primarily in SG&A expense in the Consolidated Statements of Income. During the year ended December 31, 2018, net costs paid to Novartis for migraine products were $44 million and were recorded primarily in SG&A expense in the Consolidated Statements of Income. During the years ended December 31, 2020, 2019, and 2018, royalties due to Novartis for Aimovig® were $139 million, $115 million and $43 million, respectively, and were recorded in Cost of sales in the Consolidated Statements of Income. During the years ended December 31, 2020, 2019 and 2018, royalties due from Novartis for Aimovig® were not material. As a result of certain regulatory and commercial events, we received milestone payments from Novartis of $295 million during the year ended December 31, 2018, which was recorded in Other revenues in the Consolidated Statements of Income.

Bayer HealthCare LLC

We are in a licensing arrangement with Bayer HealthCare LLC (Bayer) for Nexavar®. Nexavar® is currently marketed and sold in more than 100 countries around the world for the treatment of unresectable liver cancer and advanced kidney cancer. In the United States, Nexavar® is also approved for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

In 2020, we amended the terms of our agreement with Bayer, which transferred all our operational responsibilities outside the United States to Bayer, including commercial and medical affairs activities. Prior to the amendment of the agreement, we shared equally in the profits outside the United States, excluding Japan. In lieu of this profit share, Bayer now pays us a royalty on sales of Nexavar® at a percentage rate in the low 30s. The rights to develop and market Nexavar® in Japan are reserved to Bayer. In the United States, Bayer pays us a royalty on sales of Nexavar® at a percentage rate in the high 30s.

The agreement with Bayer will terminate at the later of the date when patents expire that were issued in connection with product candidates discovered under the agreement or on the last day that we or Bayer market or sell products commercialized under the agreement anywhere in the world. Patents related to Nexavar® began to expire in 2020.

As a result of the 2020 amendment to the collaboration agreement, royalties due from Bayer for Nexavar® were $217 million and net profits were not material for the year ended December 31, 2020. During the years ended December 31, 2019 and 2018, royalties due from Bayer for Nexavar® were $79 million and $91 million, respectively. During the years ended December 31, 2019 and 2018, Amgen recorded Nexavar® net profits of $210 million and $164 million, respectively. Royalties and profit share due from Nexavar® were recorded in Other revenues in the Consolidated Statements of Income. Net R&D expenses related to the agreement were not material for the years ended December 31, 2020, 2019 and 2018.

Other

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

9. Investments

Available-for-sale investments

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

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

Types of securities as of December 31, 2019	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 359	$ 1	$ —	$ 360
U.S. Treasury bills	—	—	—	—
Corporate debt securities:				
Financial	1,108	13	—	1,121
Industrial	824	10	—	834
Other	195	3	—	198
Residential-mortgage-backed securities	181	1	—	182
Money market mutual funds	5,250	—	—	5,250
Other short-term interest-bearing securities	289	—	—	289
Total available-for-sale investments	$ 8,206	$ 28	$ —	$ 8,234

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

	December 31,	
Consolidated Balance Sheets locations	2020	2019
Cash and cash equivalents	$ 5,464	$ 5,360
Marketable securities	4,381	2,874
Total available-for-sale investments	$ 9,845	$ 8,234

Cash and cash equivalents in the above table excludes bank account cash of $802 million and $677 million as of December 31, 2020 and 2019, respectively.

The fair values of available-for-sale investments by contractual maturity, except for mortgage- and asset-backed securities that do not have a single maturity date, were as follows (in millions):

	December 31,	
Contractual maturities	**2020**	**2019**
Maturing in one year or less	$ 9,795	$ 5,629
Maturing after one year through three years	50	2,304
Maturing after three years through five years	—	119
Residential-mortgage-backed securities	—	182
Total available-for-sale investments	$ 9,845	$ 8,234

For the years ended December 31, 2020, 2019 and 2018, realized gains on interest-bearing securities were $37 million, $92 million and $29 million, respectively, and realized losses on interest-bearing securities were $4 million, $36 million and $394 million, respectively. Realized gains and losses on interest-bearing securities are recorded in Interest and other income, net, in the Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

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

We review our available-for-sale investments for declines in fair value below our cost basis each quarter or whenever circumstances indicate that the cost basis of an asset may not be recoverable and assess whether the decline was due to credit-related factors or other factors. Our evaluation is based on a number of factors, including the extent to which the fair value is below our cost basis as well as adverse conditions related specifically to the security, such as any changes to the credit rating of the security and the intent to sell or whether we will more likely than not be required to sell the security before recovery of its amortized cost basis. Our assessment of whether a security is impaired could change in the future based on new developments or changes in assumptions related to that particular security.

Equity securities

We held investments in equity securities with readily determinable fair values of $477 million and $303 million as of December 31, 2020 and 2019, respectively, which are included in Other assets in the Consolidated Balance Sheets. For the years ended December 31, 2020, 2019 and 2018, net unrealized gains on publicly traded securities were $174 million, $112 million and $24 million, respectively. Realized gains and losses on publicly traded securities for the years ended December 31, 2020, 2019 and 2018, were not material.

We held investments of $203 million and $176 million in equity securities without readily determinable fair values as of December 31, 2020 and 2019, respectively, which are included in Other assets in the Consolidated Balance Sheets. Gains and losses recognized on these securities, including adjustments to the carrying values of these securities, were not material for the years ended December 31, 2020, 2019 and 2018.

Equity Method Investments

Limited partnership investments

We held limited partnership investments of $496 million and $320 million as of December 31, 2020 and 2019, respectively, which are included in Other assets in the Consolidated Balance Sheets. These investments, primarily investment funds of early-stage biotechnology companies, are accounted for by using the equity method of accounting and are measured by using our proportionate share of the net asset values of the underlying investments held by the limited partnerships as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of December 31, 2020, unfunded additional commitments to be made for these investments during the next several years were not material. For the years ended December 31, 2020, 2019 and 2018 net gains recognized from our limited partnership investments were $241 million, $27 million and $91 million, respectively.

BeiGene

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

During the year ended December 31, 2020, we recognized an increase in the carrying value of our investment by purchasing additional shares to maintain our ownership interest for an aggregate cost of $569 million and recognized $34 million for the impact of other BeiGene ownership transactions. The carrying value of the investment during the year ended December 31, 2020, was reduced for our share of BeiGene's net losses of $229 million and amortization of the basis difference of $109 million.

As of December 31, 2020, the carrying value and fair value of our approximately 20.5% ownership interest in BeiGene totaled $2.9 billion and $4.9 billion, respectively. We believe that as of December 31, 2020, the carrying value of our equity investment in BeiGene is fully recoverable. For information on a collaboration agreement we entered into with BeiGene in connection with this investment, see Note 8, Collaborations.

10. Inventories

Inventories consisted of the following (in millions):

	December 31,	
	2020	2019
Raw materials	$ 486	$ 358
Work in process	2,437	2,227
Finished goods	970	999
Total inventories	$ 3,893	$ 3,584

11. Property, plant and equipment

Property, plant and equipment consisted of the following (dollar amounts in millions):

		December 31,	
	Useful life (in years)	2020	2019
Land	—	$ 259	$ 263
Buildings and improvements	10-40	3,857	3,757
Manufacturing equipment	8-12	2,865	2,655
Laboratory equipment	8-12	1,257	1,236
Fixed equipment	12	2,406	2,338
Capitalized software	3-5	1,216	1,154
Other	5-10	1,091	975
Construction in progress	—	915	907
Property, plant and equipment, gross		13,866	13,285
Less accumulated depreciation and amortization		(8,977)	(8,357)
Property, plant and equipment, net		$ 4,889	$ 4,928

During the years ended December 31, 2020, 2019 and 2018, we recognized depreciation and amortization expense associated with our property, plant and equipment of $640 million, $635 million and $630 million, respectively.

Geographic information

Certain geographic information with respect to property, plant and equipment, net (long-lived assets), was as follows (in millions):

	December 31,	
	2020	2019
United States	$ 2,473	$ 2,433
Puerto Rico	1,331	1,402
ROW	1,085	1,093
Total property, plant and equipment, net	$ 4,889	$ 4,928

12. Goodwill and other intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows (in millions):

	December 31,	
	2020	2019
Beginning balance	$ 14,703	$ 14,699
Addition from acquisitions	—	26
Currency translation adjustments	(14)	(22)
Ending balance	$ 14,689	$ 14,703

Other intangible assets

Other intangible assets consisted of the following (in millions):

	December 31,					
	2020			2019		
	Gross carrying amounts	Accumulated amortization	Other intangible assets, net	Gross carrying amounts	Accumulated amortization	Other intangible assets, net
Finite-lived intangible assets:						
Developed-product-technology rights	$ 25,591	$ (10,564)	$ 15,027	$ 25,575	$ (8,322)	$ 17,253
Licensing rights	3,743	(2,791)	952	3,761	(2,398)	1,363
Marketing-related rights	1,367	(1,041)	326	1,382	(965)	417
R&D technology rights	1,317	(1,065)	252	1,273	(947)	326
Total finite-lived intangible assets	32,018	(15,461)	16,557	31,991	(12,632)	19,359
Indefinite-lived intangible assets:						
IPR&D	30	—	30	54	—	54
Total other intangible assets	$ 32,048	$ (15,461)	$ 16,587	$ 32,045	$ (12,632)	$ 19,413

Developed-product-technology rights consists of rights related to marketed products acquired in acquisitions. Licensing rights consists primarily of contractual rights acquired in acquisitions to receive future milestone, royalty and profit-sharing payments; capitalized payments to third parties for milestones related to regulatory approvals to commercialize products; and up-front payments associated with royalty obligations for marketed products. Marketing-related rights consists primarily of rights related to the sale and distribution of marketed products. R&D technology rights pertains to technologies used in R&D that have alternative future uses.

IPR&D consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. All IPR&D projects have major risks and uncertainties associated with the timely and successful completion of the development and commercialization of product candidates, including our ability to confirm safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not permitted to market a human therapeutic without obtaining regulatory approvals, and such approvals require the completion of clinical trials that demonstrate that a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans as well as competitive product launches, affect the revenues a product can generate. Consequently, the eventual realized values, if any, of acquired IPR&D projects may vary from their estimated fair values. We review IPR&D projects for impairment annually, whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable and upon the establishment of technological feasibility or regulatory approval.

During the years ended December 31, 2020, 2019 and 2018, we recognized amortization associated with our finite-lived intangible assets of $2.8 billion, $1.4 billion and $1.3 billion, respectively. Amortization of intangible assets is included primarily in Cost of sales in the Consolidated Statements of Income. The total estimated amortization for our finite-lived intangible assets for the years ending December 31, 2021, 2022, 2023, 2024 and 2025, are $2.6 billion, $2.5 billion, $2.4 billion, $2.4 billion and $2.2 billion, respectively.

13. Leases

On January 1, 2019, we adopted a new accounting standard that amends the guidance for the accounting and reporting of leases. Certain required disclosures have been made on a prospective basis in accordance with the standard's guidance. See Note 1, Summary of significant accounting policies.

We lease certain facilities and equipment related primarily to administrative, R&D and sales and marketing activities. Leases with terms of 12 months or less are expensed on a straight-line basis over the term and are not recorded in the Consolidated Balance Sheets.

Most leases include one or more options to renew, with renewal terms that may extend the lease term up to seven years. The exercise of lease renewal options is at our sole discretion. In addition, some of our lease agreements include rental payments adjusted periodically for inflation. Our lease agreements neither contain residual value guarantees nor impose significant restrictions or covenants. We sublease certain real estate to third parties. Our sublease portfolio consists of operating leases from former R&D and administrative space.

The following table summarizes information related to our leases, all of which are classified as operating, included in our Consolidated Balance Sheets (in millions):

	December 31,	
Consolidated Balance Sheets locations	**2020**	**2019**
Assets:		
Other assets	$ 408	$ 469
Liabilities:		
Accrued liabilities	$ 153	$ 140
Other noncurrent liabilities	306	388
Total lease liabilities	$ 459	$ 528

The components of net lease costs were as follows (in millions):

	Years ended December 31,	
Lease costs	**2020**	**2019**
Operating[(1)]	$ 223	$ 204
Sublease income	(34)	(33)
Total net lease costs	$ 189	$ 171

(1) Includes short-term leases and variable lease costs, which were not material for the years ended December 31, 2020 and 2019.

Maturities of lease liabilities as of December 31, 2020, were as follows (in millions):

Maturity dates	Amounts
2021	$ 164
2022	132
2023	105
2024	36
2025	15
Thereafter	36
Total lease payments[1]	488
Less imputed interest	(29)
Present value of lease liabilities	$ 459

[1] Includes future rental commitments for abandoned leases of $133 million. We expect to receive total future rental income of $107 million related to noncancelable subleases for abandoned facilities.

The weighted-average remaining lease terms and weighted-average discount rates were as follows:

	December 31,	
	2020	2019
Weighted-average remaining lease term (in years)	3.7	4.1
Weighted-average discount rate	3.1 %	3.3 %

Cash and noncash information related to our leases was as follows (in millions):

	Years ended December 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 177	$ 148
ROU assets obtained in exchange for lease obligations:		
Operating leases	$ 101	$ 163

As of December 31, 2020, we have entered into leases that have not yet commenced, with total undiscounted future lease payments of $339 million. These leases will commence in 2021 with lease terms from 30 months to 15 years.

Rental expense on operating leases under the prior lease guidance for the year ended December 31, 2018, was $166 million.

14. Other current assets and accrued liabilities

Other current assets consisted of the following (in millions):

	December 31,	
	2020	2019
Prepaid expenses	$ 1,156	$ 939
Corporate partner receivables	583	485
Tax receivables	216	186
Other	124	278
Total other current assets	$ 2,079	$ 1,888

Accrued liabilities consisted of the following (in millions):

	December 31,	
	2020	2019
Sales deductions	$ 4,801	$ 3,880
Employee compensation and benefits	1,098	981
Dividends payable	1,018	946
Income taxes payable	828	557
Sales returns reserve	474	564
Other	1,922	1,583
Total accrued liabilities	$ 10,141	$ 8,511

15. Financing arrangements

Our borrowings consisted of the following (in millions):

	December 31,	
	2020	2019
4.50% notes due 2020 (4.50% 2020 Notes)	—	300
2.125% notes due 2020 (2.125% 2020 Notes)	—	750
Floating Rate Notes due 2020	—	300
2.20% notes due 2020 (2.20% 2020 Notes)	—	700
3.45% notes due 2020 (3.45% 2020 Notes)	—	900
4.10% notes due 2021 (4.10% 2021 Notes)	—	1,000
1.85% notes due 2021 (1.85% 2021 Notes)	—	750
3.875% notes due 2021 (3.875% 2021 Notes)	—	1,750
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	1,527	1,402
2.70% notes due 2022 (2.70% 2022 Notes)	500	500
2.65% notes due 2022 (2.65% 2022 Notes)	1,500	1,500
3.625% notes due 2022 (3.625% 2022 Notes)	750	750
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	791	725
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
1.90% notes due 2025 (1.90% 2025 Notes)	500	—
3.125% notes due 2025 (3.125% 2025 Notes)	1,000	1,000
2.00% €750 million notes due 2026 (2.00% 2026 euro Notes)	916	841
2.60% notes due 2026 (2.60% 2026 Notes)	1,250	1,250
5.50% £475 million notes due 2026 (5.50% 2026 pound sterling Notes)	649	630
2.20% notes due 2027 (2.20% 2027 Notes)	1,750	—
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	957	928
2.45% notes due 2030 (2.45% 2030 Notes)	1,250	—
2.30% notes due 2031 (2.30% 2031 Notes)	1,250	—
6.375% notes due 2037 (6.375% 2037 Notes)	478	552
6.90% notes due 2038 (6.90% 2038 Notes)	254	291
6.40% notes due 2039 (6.40% 2039 Notes)	333	466
3.15% notes due 2040 (3.15% 2040 Notes)	2,000	—
5.75% notes due 2040 (5.75% 2040 Notes)	373	412
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	729	974
5.65% notes due 2042 (5.65% 2042 Notes)	415	487
5.375% notes due 2043 (5.375% 2043 Notes)	185	261
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415
3.375% notes due 2050 (3.375% 2050 Notes)	2,250	—
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
2.77% notes due 2053 (2.77% 2053 Notes)	940	—
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(1,188)	(868)
Fair value adjustments	566	296
Other	5	—
Total carrying value of debt	32,986	29,903
Less current portion	(91)	(2,953)
Total long-term debt	$ 32,895	$ 26,950

There are no material differences between the effective interest rates and the coupon rates of any of our borrowings, except for the 4.563% 2048 Notes, the 4.663% 2051 Notes and the 2.77% 2053 Notes, which have effective interest rates of 6.3%, 5.6% and 5.2%, respectively.

Under the terms of all of our outstanding notes, except our Other notes due 2097, in the event of a change-in-control triggering event we may be required to purchase all or a portion of these debt securities at prices equal to 101% of the principal amounts of the notes plus accrued and unpaid interest. In addition, all of our outstanding notes—except our 0.41% 2023 Swiss franc Bonds and Other notes due 2097—may be redeemed at any time at our option—in whole or in part—at the principal amounts of the notes being redeemed plus accrued and unpaid interest and make-whole amounts, which are defined by the terms of the notes. Certain of the redeemable notes do not require the payment of make-whole amounts if redeemed during a specified period of time immediately prior to the maturity of the notes. Such time periods range from one month to six months prior to maturity.

Debt issuances

During the year ended December 31, 2020, we issued debt securities in the following offerings:

- In February 2020, we issued $5.0 billion of debt consisting of $500 million of the 1.90% 2025 Notes, $750 million of the 2.20% 2027 Notes, $1.25 billion of the 2.45% 2030 Notes, $1.25 billion of the 3.15% 2040 Notes and $1.25 billion of the 3.375% 2050 Notes.
- In May 2020, we issued $4.0 billion of debt consisting of $1.0 billion of the 2.20% 2027 Notes, $750 million of the 3.15% 2040 Notes and $1.0 billion of the 3.375% 2050 Notes, which represents a further issuance of, and which forms a single series with, each of the corresponding series of notes issued in February 2020, and $1.25 billion of the 2.30% 2031 Notes.

We did not issue any debt or debt securities during the years ended December 31, 2019 and 2018.

Debt repayments/redemptions

We made debt repayments/redemptions during the years ended December 31, 2020, 2019 and 2018 as follows:

- In 2020, we repaid/redeemed $6.5 billion of debt, including the repayment at maturity of the $300 million aggregate principal amount of the 4.50% 2020 Notes, the $750 million aggregate principal amount of the 2.125% 2020 Notes, the $300 million Floating Rate Notes due 2020 and the $700 million aggregate principal amount of the 2.20% 2020 Notes. In connection with the redemption of the $900 million aggregate principal amount of the 3.45% 2020 Notes, the $1.0 billion aggregate principal balance of the 4.10% 2021 Notes, the $750 million aggregate principal balance of the 1.85% 2021 Notes and the $1.75 billion aggregate principal balance of the 3.875% 2021 Notes, we paid a total of $96 million in make-whole amounts plus associated accrued and unpaid interest, all of which was recognized in Interest expense, net, in the Consolidated Statements of Income.
- In 2019, we repaid $4.5 billion of debt, including the $1.4 billion aggregate principal amount of the 2.20% 2019 Notes, the $1.0 billion aggregate principal amount of the 5.70% 2019 Notes, the €675 million aggregate principal amount ($864 million upon settlement of the related cross-currency swap) of the 2.125% 2019 euro Notes, the $700 million aggregate principal amount of the 1.90% 2019 Notes and the $550 million Floating Rate Notes due 2019.
- In 2018, we repaid $1.1 billion of debt, including the $500 million aggregate principal amount of the 6.15% 2018 Notes and the €550 million aggregate principal amount of the 4.375% 2018 Notes revalued at $621 million upon maturity.

Interest rate swaps

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted fixed-rate interest coupons for certain of our debt issuances to floating LIBOR-based coupons over the lives of the respective notes. These interest rate swap contracts qualified and are designated as fair value hedges.

In connection with the redemption of certain of the notes discussed above, associated interest rate swap contracts with an aggregate notional value of $3.65 billion were terminated. In addition, because of historically low interest rates, during the year ended December 31, 2020, we terminated interest rate swaps with an aggregate notional amount of $5.2 billion that hedged the 3.625% 2024 Notes, the 2.60% 2026 Notes, the 4.663% 2051 Notes and portions of the 3.625% 2022 Notes and the 3.125% 2025 Notes, which resulted in the receipt of $576 million of cash and reduced counterparty credit risk. Immediately following the terminations of these contracts, we entered into new interest rate swap agreements at then-current interest rates on the same $5.2 billion principal amount of notes. See Note 18, Derivative instruments.

The effective interest rates on notes for which we have entered into interest rate swap contracts and the related notional amounts of these contracts were as follows (dollar amounts in millions):

	December 31, 2020		December 31, 2019	
Notes	Notional amounts	Effective interest rates	Notional amounts	Effective interest rates
3.45% 2020 Notes	$ —	LIBOR + 1.1%	$ 900	LIBOR + 1.1%
4.10% 2021 Notes	—	LIBOR + 1.7%	1,000	LIBOR + 1.7%
3.875% 2021 Notes	—	LIBOR + 2.0%	1,750	LIBOR + 2.0%
3.625% 2022 Notes	750	LIBOR + 2.7%	750	LIBOR + 1.6%
3.625% 2024 Notes	1,400	LIBOR + 3.2%	1,400	LIBOR + 1.4%
3.125% 2025 Notes	1,000	LIBOR + 1.8%	1,000	LIBOR + 0.9%
2.60% 2026 Notes	1,250	LIBOR + 1.8%	1,250	LIBOR + 0.3%
4.663% 2051 Notes[(1)]	1,500	LIBOR + 2.6%	1,500	LIBOR + 0.0%
Total notional amounts	$ 5,900		$ 9,550	

(1) Excludes an additional 1.5% of interest for the difference between the coupon rate paid to noteholders and the fixed rate received under the interest rate swap contracts.

Debt exchange

In 2020, we completed a private offering to exchange portions of certain outstanding senior notes due 2037 through 2043 (collectively, Old Notes), listed below, for the $940 million principal amount of the newly issued 2.77% 2053 Notes (the Exchange Offer).

The following principal amounts of each series of Old Notes were validly tendered and subsequently cancelled in connection with the Exchange Offer (in millions):

	Principal amount exchanged
6.375% 2037 Notes	$ 74
6.90% 2038 Notes	37
6.40% 2039 Notes	133
5.75% 2040 Notes	39
5.15% 2041 Notes	245
5.65% 2042 Notes	72
5.375% 2043 Notes	76

The 2.77% 2053 Notes bear interest at a lower fixed coupon rate while requiring higher principal repayment at a later maturity date as compared to those of the Old Notes that were exchanged. There were no other significant changes to the terms between the Old Notes and the 2.77% 2053 Notes. In connection with the Exchange Offer, $85 million was paid to holders of the Old Notes (the cash consideration).

The Exchange Offer was accounted for as a debt modification, and accordingly, deferred financing costs and discounts associated with the Old Notes, the cash consideration and the $264 million discount associated with the 2.77% 2053 Notes are being accreted over the term of these newly issued notes and recorded as Interest expense, net, in the Consolidated Statements of Income.

Cross-currency swaps

In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. The terms of these contracts effectively convert the interest payments and principal repayments on our 1.25% 2022 euro Notes, 0.41% 2023 Swiss franc Bonds, 2.00% 2026 euro Notes, 5.50% 2026 pound sterling Notes and 4.00% 2029 pound sterling Notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts have been designated as cash flow hedges. For information regarding the terms of these contracts, see Note 18, Derivative instruments.

Shelf registration statement and other facilities

As of December 31, 2020, we have a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. As of December 31, 2020 and 2019, we had no amounts outstanding under our commercial paper program.

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

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

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which requires us to maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2020.

Contractual maturities of debt obligations

The aggregate contractual maturities of all borrowings due subsequent to December 31, 2020, are as follows (in millions):

Maturity dates	Amounts
2021	$ —
2022	4,277
2023	1,541
2024	1,400
2025	1,500
Thereafter	24,890
Total	$ 33,608

Interest costs

Interest costs are expensed as incurred except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest costs capitalized for the years ended December 31, 2020, 2019 and 2018, were not material. Interest paid, including the ongoing impact of interest rate and cross-currency swap contracts, during the years ended December 31, 2020, 2019 and 2018, were $1.2 billion, $1.3 billion and $1.5 billion, respectively.

16. Stockholders' equity

Stock repurchase program

Activity under our stock repurchase program, on a trade date basis, was as follows (in millions):

	Years ended December 31,					
	2020		2019		2018	
	Shares	Dollars	Shares*	Dollars	Shares*	Dollars
First quarter	4.3	$ 933	15.9	$ 3,031	56.4	$ 10,787
Second quarter	2.6	591	13.1	2,349	18.2	3,190
Third quarter	3.0	752	6.2	1,170	8.7	1,713
Fourth quarter	5.3	1,221	5.1	1,090	11.1	2,165
Total stock repurchases	15.2	$ 3,497	40.2	$ 7,640	94.5	$ 17,855

* Total shares do not add due to rounding.

In December 2019, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $4.0 billion. As of December 31, 2020, $3.0 billion remained available under our stock repurchase program.

Dividends

Our Board of Directors declared quarterly dividends per share of $1.60, $1.45 and $1.32, which were paid in each of the four quarters of 2020, 2019 and 2018, respectively.

Historically, we have declared dividends in December of each year, which were paid in the first quarter of the following fiscal year and in March, July and October, which were paid in the second, third and fourth quarters, respectively, of the same fiscal year. Additionally, on December 16, 2020, the Board of Directors declared a quarterly cash dividend of $1.76 per share of common stock, which will be paid on March 8, 2021, to all stockholders of record as of the close of business on February 15, 2021.

Accumulated other comprehensive loss

The components of AOCI were as follows (in millions):

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2017	$ (529)	$ (6)	$ (144)	$ —	$ (679)
Cumulative effect of change in accounting principle, net of tax	—	—	(9)	—	(9)
Foreign currency translation adjustments	(141)	—	—	—	(141)
Unrealized gains (losses)	—	61	(556)	—	(495)
Reclassification adjustments to income	—	262	365	—	627
Other losses	—	—	—	(2)	(2)
Income taxes	—	(76)	6	—	(70)
Balance as of December 31, 2018	(670)	241	(338)	(2)	(769)
Foreign currency translation adjustments	(48)	—	—	—	(48)
Unrealized gains	—	127	424	—	551
Reclassification adjustments to income	—	(211)	(56)	—	(267)
Other losses	—	—	—	(5)	(5)
Income taxes	—	18	(8)	—	10
Balance as of December 31, 2019	(718)	175	22	(7)	(528)
Foreign currency translation adjustments	9	—	—	—	9
Unrealized (losses) gains	—	(61)	6	—	(55)
Reclassification adjustments to income	—	(501)	(33)	—	(534)
Other losses	—	—	—	(7)	(7)
Income taxes	—	124	6	—	130
Balance as of December 31, 2020	$ (709)	$ (263)	$ 1	$ (14)	$ (985)

With respect to the table above, income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for cash flow hedges were a $14 million benefit and a $110 million benefit in 2020, a $28 million expense and a $46 million benefit in 2019 and a $21 million expense and a $55 million expense in 2018, respectively. Income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for available-for-sale securities were a $1 million expense and a $7 million benefit in 2020, a $22 million expense and a $14 million benefit in 2019 and a $9 million benefit and a $3 million expense in 2018, respectively.

Reclassifications out of AOCI and into earnings were as follows (in millions):

Components of AOCI	Years ended December 31, 2020	2019	2018	Consolidated Statements of Income locations
Cash flow hedges:				
Foreign currency contract gains (losses)	$ 178	$ 101	$ (21)	Product sales
Cross-currency swap contract gains (losses)	323	110	(241)	Interest and other income, net
	501	211	(262)	Income before income taxes
	(110)	(46)	55	Provision for income taxes
	$ 391	$ 165	$ (207)	Net income
Available-for-sale securities:				
Net realized gains (losses)	$ 33	$ 56	$ (365)	Interest and other income, net
	(7)	(14)	3	Provision for income taxes
	$ 26	$ 42	$ (362)	Net income

Other

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. As of December 31, 2020 and 2019, no shares of preferred stock were issued or outstanding.

17. Fair value measurement

To estimate the fair value of our financial assets and liabilities, we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing an asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing an asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access

Level 2 — Valuations for which all significant inputs are observable either directly or indirectly—other than Level 1 inputs

Level 3 — Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

The fair values of each major class of the Company's financial assets and liabilities measured at fair value on a recurring basis were as follows (in millions):

Fair value measurement as of December 31, 2020, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	$ 130	$ —	$ —	$ 130
U.S. Treasury bills	4,948	—	—	4,948
Corporate debt securities:				
Financial	—	—	—	—
Industrial	—	—	—	—
Other	—	—	—	—
Residential-mortgage-backed securities	—	—	—	—
Money market mutual funds	4,765	—	—	4,765
Other short-term interest-bearing securities	—	2	—	2
Equity securities	477	—	—	477
Derivatives:				
Foreign currency contracts	—	28	—	28
Cross-currency swap contracts	—	255	—	255
Interest rate swap contracts	—	66	—	66
Total assets	$ 10,320	$ 351	$ —	$ 10,671
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 237	$ —	$ 237
Cross-currency swap contracts	—	318	—	318
Interest rate swap contracts	—	15	—	15
Contingent consideration obligations	—	—	33	33
Total liabilities	$ —	$ 570	$ 33	$ 603

Fair value measurement as of December 31, 2019, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	$ 360	$ —	$ —	$ 360
U.S. Treasury bills	—	—	—	—
Corporate debt securities:				
Financial	—	1,121	—	1,121
Industrial	—	834	—	834
Other	—	198	—	198
Residential-mortgage-backed securities	—	182	—	182
Money market mutual funds	5,250	—	—	5,250
Other short-term interest-bearing securities	—	289	—	289
Equity securities	303	—	—	303
Derivatives:				
Foreign currency contracts	—	224	—	224
Cross-currency swap contracts	—	66	—	66
Interest rate swap contracts	—	259	—	259
Total assets	$ 5,913	$ 3,173	$ —	$ 9,086
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 31	$ —	$ 31
Cross-currency swap contracts	—	315	—	315
Interest rate swap contracts	—	—	—	—
Contingent consideration obligations	—	—	61	61
Total liabilities	$ —	$ 346	$ 61	$ 407

Interest-bearing and equity securities

The fair values of our U.S. Treasury securities, money market mutual funds and equity securities are based on quoted market prices in active markets, with no valuation adjustment.

We estimate the fair values of our corporate debt securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry-standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

We estimate the fair values of our residential-mortgage-backed securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry-standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment or default projections based on historical data; and other observable inputs.

We value our other short-term interest-bearing securities at amortized cost, which approximates fair value given their near-term maturity dates.

Derivatives

All of our foreign currency forward and option derivative contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A– or equivalent by Standard & Poor's Financial Services (S&P), Moody's Investors Service, Inc. (Moody's) or Fitch Ratings, Inc. (Fitch). We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. These inputs, when applicable, are at commonly quoted intervals. See Note 18, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. See Note 18, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by using an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include LIBOR, swap rates and obligor credit default swap rates. See Note 18, Derivative instruments.

During the years ended December 31, 2020 and 2019, there were no transfers of assets or liabilities between fair value measurement levels, and there were no material remeasurements to the fair values of assets and liabilities that are not measured at fair value on a recurring basis. During the year ended December 31, 2018, we discontinued the internal development of a program that resulted in an impairment of an IPR&D asset of $330 million, which was recognized in Other operating expenses in the Consolidated Statements of Income and included in Other items, net, in the Consolidated Statements of Cash Flows.

Summary of the fair values of other financial instruments

Cash equivalents

The fair values of cash equivalents approximate their carrying values due to the short-term nature of such financial instruments.

Borrowings

We estimated the fair values of our borrowings by using Level 2 inputs. As of December 31, 2020 and 2019, the aggregate fair values of our borrowings were $39.4 billion and $33.7 billion, respectively, and the carrying values were $33.0 billion and $29.9 billion, respectively.

Investment in BeiGene

We estimated the fair value of our investment in BeiGene by using Level 1 inputs. As of December 31, 2020, the fair value and carrying value were $4.9 billion and $2.9 billion, respectively.

18. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we use or have used certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We do not use derivatives for speculative trading purposes.

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates associated primarily with our euro-denominated international product sales. Increases and decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are partially offset by corresponding increases and decreases in the cash flows from our international operating expenses resulting from these foreign currency exchange rate movements. To further reduce our exposure to foreign currency exchange rate fluctuations with regard to our international product sales, we enter into foreign currency forward and option contracts to hedge a portion of our projected international product sales primarily over a three-year time horizon, with, at any given point in time, a higher percentage of nearer-term projected product sales being hedged than in successive periods.

As of December 31, 2020, 2019 and 2018, we had outstanding foreign currency forward contracts with aggregate notional amounts of $5.1 billion, $5.0 billion and $4.5 billion, respectively. As of December 31, 2018 we had outstanding foreign currency option contracts with aggregate notional amounts of $21 million, and no such outstanding contracts as of December 31, 2020 and 2019. We have designated these foreign currency forward and foreign currency option contracts, which are primarily euro based, as cash flow hedges. Accordingly, we report the unrealized gains and losses on these contracts in AOCI in the Consolidated Balance Sheets, and we reclassify them to Product sales in the Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term debt denominated in foreign currencies, we enter into cross-currency swap contracts. Under the terms of such contracts, we paid euros, pounds sterling and Swiss francs and received U.S. dollars for the notional amounts at the inception of the contracts; and based on these notional amounts, we exchange interest payments at fixed rates over the lives of the contracts by paying U.S. dollars and receiving euros, pounds sterling and Swiss francs. In addition, we will pay U.S. dollars to and receive euros, pounds sterling and Swiss francs from the counterparties at the maturities of the contracts for these same notional amounts. The terms of these contracts correspond to the related hedged debt, thereby effectively converting the interest payments and principal repayment on the debt from euros, pounds sterling and Swiss francs to U.S. dollars. We have designated these cross-currency swap contracts as cash flow hedges. Accordingly, the unrealized gains and losses on these contracts are reported in AOCI in the Consolidated Balance Sheets and reclassified to Interest and other income, net, in the Consolidated Statements of Income in the same periods during which the hedged debt affects earnings.

The notional amounts and interest rates of our cross-currency swaps as of December 31, 2020, were as follows (notional amounts in millions):

	Foreign currency			U.S. dollars	
Hedged notes	**Notional amounts**		**Interest rates**	**Notional amounts**	**Interest rates**
1.25% 2022 euro Notes	€	1,250	1.3 %	$ 1,388	3.2 %
0.41% 2023 Swiss franc Bonds	CHF	700	0.4 %	$ 704	3.4 %
2.00% 2026 euro Notes	€	750	2.0 %	$ 833	3.9 %
5.50% 2026 pound sterling Notes	£	475	5.5 %	$ 747	6.0 %
4.00% 2029 pound sterling Notes	£	700	4.0 %	$ 1,111	4.5 %

During the year ended December 31, 2019, our 2.125% 2019 euro Notes matured, and the related cross-currency swaps were settled.

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Consolidated Balance Sheets and are amortized into Interest expense, net, in the Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the year ended December 31, 2020, and amounts expected to be recognized during the subsequent 12 months are not material.

The unrealized losses and gains recognized in AOCI for our derivative instruments designated as cash flow hedges were as follows (in millions):

	Years ended December 31,		
Derivatives in cash flow hedging relationships	**2020**	**2019**	**2018**
Foreign currency contracts	$ (251)	$ 148	$ 348
Cross-currency swap contracts	190	(21)	(287)
Forward interest rate contracts	—	—	—
Total unrealized (losses) gains	$ (61)	$ 127	$ 61

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified for and were designated as fair value hedges. These interest rate swap contracts effectively convert fixed-rate coupons to floating-rate LIBOR-based coupons over the terms of the related hedge contracts. As of December 31, 2020 and 2019, we had interest rate swap contracts with aggregate notional amounts of $5.9 billion and $9.6 billion, respectively, that hedge certain portions of our long-term debt issuances.

Interest rate swaps with an aggregate notional value of $3.7 billion were terminated during the year ended December 31, 2020, in connection with the redemption of certain of our notes. The terminations of these interest rate swaps resulted in a gain of $40 million, recognized in Interest expense, net, in the Consolidated Statements of Income. Additionally, we terminated $5.2 billion aggregate notional amount of interest rate swaps, which resulted in the receipt of $576 million from the counterparties that was included in Net cash provided by operating activities in the Consolidated Statements of Cash Flows for the year ended December 31, 2020. This amount will be recognized as a reduction in Interest expense, net, in the Consolidated Statements of Income over the remaining life of the underlying notes. Immediately following the terminations of these interest rate swap contracts, we entered into new interest rate swap agreements at then-current interest rates on the same $5.2 billion principal amount of notes. See Note 15, Financing arrangements, for information on our interest rate swaps.

For interest rate swap contracts that qualify for and are designated as fair value hedges, we recognize in Interest expense, net, in the Consolidated Statements of Income the unrealized gain or loss on the derivative resulting from the change in fair value during the period, as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. If a hedging relationship involving an interest rate swap contract is terminated, the gain or loss realized on contract termination is recorded as an adjustment to the carrying value of the debt and amortized into Interest expense, net, over the remaining life of the previously hedged debt.

The hedged liabilities and related cumulative-basis adjustments for fair value hedges of those liabilities were recorded in the Consolidated Balance Sheets as follows (in millions):

	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
	December 31,		December 31,	
Consolidated Balance Sheets locations	2020	2019	2020	2019
Current portion of long-term debt	$ 89	$ 903	$ 89	$ 4
Long-term debt	$ 6,258	$ 8,814	$ 477	$ 292

[1] Current portion of long-term debt includes $89 million of carrying value with discontinued hedging relationships as of December 31, 2020. Long-term debt includes $525 million and $136 million of carrying value with discontinued hedging relationships as of December 31, 2020, and December 31, 2019, respectively.

[2] Current portion of long-term debt includes $89 million of hedging adjustments on discontinued hedging relationships as of December 31, 2020. Long-term debt includes $425 million and $36 million of hedging adjustments on discontinued hedging relationships as of December 31, 2020, and December 31, 2019, respectively.

Impact of hedging transactions

The following tables summarize the amounts recorded in income and expense line items and the effects thereon from fair value and cash flow hedging, including discontinued hedging relationships (in millions):

	Year ended December 31, 2020		
	Product sales	Interest and other income, net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 24,240	$ 256	$ (1,262)
The effects of cash flow and fair value hedging:			
Gains on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ 178	$ —	$ —
Cross-currency swap contracts	$ —	$ 323	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ 315
Derivatives designated as hedging instruments	$ —	$ —	$ (204)

	Year ended December 31, 2019		
	Product sales	Interest and other income, net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 22,204	$ 753	$ (1,289)
The effects of cash flow and fair value hedging:			
Gains on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ 101	$ —	$ —
Cross-currency swap contracts	$ —	$ 110	$ —
(Losses) gains on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ (349)
Derivatives designated as hedging instruments	$ —	$ —	$ 352

	Year ended December 31, 2018		
	Product sales	Interest and other income (expense), net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 22,533	$ 674	$ (1,392)
The effects of cash flow and fair value hedging:			
(Losses) on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ (21)	$ —	$ —
Cross-currency swap contracts	$ —	$ (241)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ 65
Derivatives designated as hedging instruments	$ —	$ —	$ (42)

[1] Gains on hedged items do not completely offset losses on the related designated hedging instruments due to amortization of the cumulative amounts of fair value hedging adjustments included in the carrying amount of the hedged debt for discontinued hedging relationships and the recognition of gains on terminated hedges where the corresponding hedged item was paid down in the period.

No portions of our cash flow hedge contracts were excluded from the assessment of hedge effectiveness. As of December 31, 2020, we expected to reclassify $136 million of net losses on our foreign currency and cross-currency swap contracts out of AOCI and into earnings during the next 12 months.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations in certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. Most of these exposures are hedged on a month-to-month basis. As of December 31, 2020, 2019 and 2018, the total notional amounts of these foreign currency forward contracts were $1.0 billion, $1.2 billion and $737 million, respectively. Gains and losses recognized in earnings for our derivative instruments not designated as hedging instruments were not material for the years ended December 31, 2020, 2019 and 2018.

The fair values of derivatives included in the Consolidated Balance Sheets were as follows (in millions):

	Derivative assets		Derivative liabilities	
December 31, 2020	Consolidated Balance Sheets locations	Fair values	Consolidated Balance Sheets locations	Fair values
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 28	Accrued liabilities/ Other noncurrent liabilities	$ 237
Cross-currency swap contracts	Other current assets/ Other assets	255	Accrued liabilities/ Other noncurrent liabilities	318
Interest rate swap contracts	Other current assets/ Other assets	66	Accrued liabilities/ Other noncurrent liabilities	15
Total derivatives designated as hedging instruments		349		570
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	—	Accrued liabilities	—
Total derivatives not designated as hedging instruments		—		—
Total derivatives		$ 349		$ 570

	Derivative assets		Derivative liabilities	
December 31, 2019	Consolidated Balance Sheets locations	Fair values	Consolidated Balance Sheets locations	Fair values
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 223	Accrued liabilities/ Other noncurrent liabilities	$ 31
Cross-currency swap contracts	Other current assets/ Other assets	66	Accrued liabilities/ Other noncurrent liabilities	315
Interest rate swap contracts	Other current assets/ Other assets	259	Accrued liabilities/ Other noncurrent liabilities	—
Total derivatives designated as hedging instruments		548		346
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	1	Accrued liabilities	—
Total derivatives not designated as hedging instruments		1		—
Total derivatives		$ 549		$ 346

Our derivative contracts that were in liability positions as of December 31, 2020, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our, or the surviving entity's, creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right but not the obligation to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the contracts may be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

The cash flow effects of our derivative contracts in the Consolidated Statements of Cash Flows are included in Net cash provided by operating activities, except for the settlement of notional amounts of cross-currency swaps, which are included in Net cash used in financing activities.

19. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See Part I, Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations.* We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote.

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Our legal proceedings involve various aspects of our business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing, in which we could incur a liability, our opponents seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process, which in complex proceedings of the sort we face often extend for several years. As a result, none of the matters described in this filing, in which we could incur a liability, have progressed sufficiently through discovery and/or the development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain recent developments concerning our legal proceedings and other matters are discussed below:

Abbreviated New Drug Application (ANDA) Patent Litigation

KYPROLIS® ANDA Patent Litigation

Onyx Therapeutics, Inc. v. Cipla Limited, et al.

Between October 2016 and April 2018, Onyx Therapeutics, Inc. (Onyx Therapeutics, a wholly-owned subsidiary of Amgen), filed separate lawsuits in the U.S. District Court for the District of Delaware (the Delaware District Court) against: (1) Cipla Limited and Cipla USA, Inc. (collectively, Cipla); (2) Sagent Pharmaceuticals, Inc. (Sagent); (3) Breckenridge Pharmaceutical, Inc. (Breckenridge); and (4) Fresenius Kabi, USA LLC, Fresenius Kabi USA, Inc., Fresenius Kabi Pharmaceuticals Holding, Inc. and Fresenius Kabi Oncology Limited; (5) Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.; (6) MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (collectively, MSN); (7) Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL); (8) Qilu Pharma, Inc. and Qilu Pharmaceutical Co. Ltd. (collectively, Qilu); (9) Apotex Inc. and Apotex Corp. (Apotex); (10) InnoPharma, Inc. (InnoPharma); and (11) Aurobindo Pharma USA, Inc., each for infringement of one or more of our following patents, which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) for KYPROLIS®: U.S. Patent Nos. 7,232,818 (the '818 Patent), 7,417,042 (the '042 Patent), 7,491,704 (the '704 Patent), 7,737,112 (the '112 Patent), 8,129,346 (the '346 Patent), 8,207,125 (the '125 Patent), 8,207,126 (the '126 Patent), 8,207,127 (the '127 Patent) and 8,207,297 (the '297 Patent). Each of these lawsuits was based on each defendant's submission of an ANDA seeking U.S. Food and Drug Administration (FDA) approval to market a generic version of KYPROLIS®. In each lawsuit, Onyx Therapeutics sought an order of the Delaware District Court making any FDA approval of the respective defendant's ANDA effective no earlier than the expiration of the applicable patents. The Delaware District Court consolidated these lawsuits for purposes of discovery into a single case, *Onyx Therapeutics, Inc. v. Cipla Limited, et al*.

In January 2017, by stipulation with Onyx Therapeutics, Fresenius Kabi Pharmaceuticals Holding, Inc. and Fresenius Kabi Oncology Limited were dismissed from the lawsuit, leaving Fresenius Kabi, USA LLC and Fresenius Kabi USA, Inc. (collectively, Fresenius) as the remaining Fresenius defendants. In September 2017 and February 2018, respectively, by joint stipulation with Onyx Therapeutics, Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. were each dismissed from the lawsuit, and in February 2018, Qilu was dismissed from the lawsuit by joint stipulation between Onyx Therapeutics and Qilu. Between April and July of 2018, the Delaware District Court entered orders on stipulations between Onyx Therapeutics and each of Apotex, DRL, Sagent, Fresenius, Breckenridge, Aurobindo Pharma USA, Inc., Cipla and InnoPharma, respectively, that each defendant infringes the '042, '112, '125, '126 and '127 Patents. Onyx Therapeutics provided those defendants, either through a stipulated order or other agreement, a covenant that it would not assert patent infringement of the '818,'704,'346 and '297 Patents against certain of the respective defendants' ANDA applications and products. In June 2018, the Delaware District Court entered an order on a stipulation between Onyx Therapeutics and MSN that MSN infringes the '112 Patent. In December 2018, Apotex, DRL, Fresenius, InnoPharma, Sagent, Breckenridge, Aurobindo Pharma USA, Inc. and Cipla amended their responses to the complaints to add the defense of unclean hands and to seek declarations of unenforceability of the asserted patents based on allegations of inequitable conduct. In January 2019, MSN amended its responses to the complaints to add the defense of unclean hands.

On January 11, 2019, Onyx Therapeutics filed a separate lawsuit in the Delaware District Court against Breckenridge for infringement of the '042, '112 and '125 Patents in connection with its ANDA that seeks approval to market generic versions of KYPROLIS®. On March 4, 2019, the Delaware District Court entered an order on a stipulation between Onyx Therapeutics and Breckenridge, providing that Breckenridge infringes the asserted claims of the '042, '112 and '125 Patents, and consolidated this lawsuit against Breckenridge into the existing consolidated case, *Onyx Therapeutics, Inc. v. Cipla Limited, et al*., for all purposes.

On May 6, 2019, the Delaware District Court commenced trial in the *Onyx Therapeutics, Inc. v. Cipla Limited, et al*. consolidated case. During trial, the Delaware District Court signed consent judgments filed by Onyx Therapeutics and each of Aurobindo Pharma USA, Inc., InnoPharma, Sagent, Apotex, Fresenius, DRL and Breckenridge, in which the parties stipulated to entry of: (1) judgment dismissing with prejudice all of the parties' claims, counterclaims, affirmative defenses and demands; and (2) an injunction prohibiting infringement of the '042, '112 and '125 Patents by the manufacture, use, sale, offer to sell or importation into the United States of the applicable defendant's carfilzomib product unless specifically authorized pursuant to the applicable confidential settlement agreement. During trial, the Delaware District Court also entered a consent judgment between Onyx Therapeutics and MSN, in which the parties stipulated to entry of: (1) judgment dismissing with prejudice all of the parties' claims, counterclaims, affirmative defenses and demands; and (2) an injunction prohibiting infringement of the '112 Patent by the manufacture, use, sale, offer to sell or importation into the United States of MSN's carfilzomib product unless specifically authorized pursuant to the confidential settlement agreement. On May 16, 2019, trial concluded between Onyx Therapeutics and the lone remaining defendant, Cipla.

On May 8, 2020, consistent with its May 4, 2020 decision and order, the Delaware District Court entered final judgment in favor of Onyx Therapeutics and against Cipla on infringement, validity and enforceability of claims 23 and 24 of the ’042 Patent, claim 1 of the ’125 Patent and claim 31 of the ’112 Patent. The Delaware District Court entered judgment in favor of Cipla and against Onyx Therapeutics on Cipla’s counterclaim for invalidity of claim 32 of the ’112 Patent and ordered that the effective date of any final approval by the FDA of Cipla’s ANDA must be after expiration of the three asserted patents (the ’042, ’125 and ’112 Patents) and any regulatory exclusivity to which Onyx Therapeutics may become entitled. The final judgment includes an injunction prohibiting Cipla from making, using, offering to sell, selling or importing into the United States Cipla’s carfilzomib product during the term of the three asserted patents. On May 29, 2020, Cipla filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court). The Federal Circuit Court has set the hearing date on Cipla’s appeal for March 5, 2021.

Otezla® ANDA Patent Litigation

Amgen Inc. v. Sandoz Inc., et al.

Beginning in June 2018, Celgene filed 19 separate lawsuits in the U.S. District Court for the District of New Jersey (the New Jersey District Court) against Alkem Laboratories Ltd. (Alkem); Amneal Pharmaceuticals LLC; Annora Pharma Private Ltd. and Hetero USA Inc. (collectively, Hetero); Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. (collectively, Aurobindo); Cipla Limited (Cipla Ltd); DRL; Emcure Pharmaceuticals Ltd. and Heritage Pharmaceuticals Inc. (collectively, Emcure); Glenmark Pharmaceuticals Ltd. (Glenmark); Macleods Pharmaceuticals Ltd. (Macleods); Mankind Pharma Ltd. (Mankind); MSN Laboratories Private Limited; Pharmascience Inc. (Pharmascience); Prinston Pharmaceutical Inc. (Prinston); Sandoz Inc.; Shilpa Medicare Ltd. (Shilpa); Teva Pharmaceuticals USA, Inc. and Actavis LLC (collectively, Actavis); Torrent Pharmaceuticals Ltd. (Torrent); Unichem Laboratories, Ltd. (Unichem); and Zydus Pharmaceuticals (USA) Inc., each for infringement of one or more of the following patents: U.S. Patent Nos. 6,962,940 (the ’940 Patent), 7,208,516 (the ’516 Patent), 7,427,638 (the ’638 Patent), 7,659,302 (the ’302 Patent), 7,893,101 (the ’101 Patent), 8,455,536 (the ’536 Patent), 8,802,717 (the ’717 Patent), 9,018,243 (the ’243 Patent) and 9,872,854 (the ’854 Patent), which are listed in the Orange Book for Otezla®. Each of the defendants is seeking to market a generic version of Otezla® before expiration of the asserted patents. The New Jersey District Court consolidated these 19 lawsuits for discovery and case management purposes into a single case, *Celgene Corp. v. Sandoz Inc., et al.* Each lawsuit seeks an order of the New Jersey District Court making any FDA approval of the respective defendant’s ANDA effective no earlier than the expiration of the applicable patents.

In August 2018, Celgene filed amended complaints against Alkem, Amneal Pharmaceuticals LLC, Aurobindo, Cipla Ltd, DRL, Glenmark, Pharmascience, Sandoz Inc., Actavis, Unichem and Zydus Pharmaceuticals (USA) Inc. additionally asserting U.S. Patent No. 9,724,330 (the ’330 Patent), which is listed in the Orange Book for Otezla®. Between October 15 and November 27, 2018, Celgene filed amended complaints against Alkem, Amneal Pharmaceuticals LLC, Hetero, Aurobindo, Cipla Ltd, DRL, Emcure, Glenmark, Macleods, Mankind, MSN Laboratories Private Limited, Pharmascience, Prinston, Sandoz Inc., Actavis, Torrent, Unichem and Zydus Pharmaceuticals (USA) Inc. additionally asserting U.S. Patent No. 10,092,541 (the ’541 Patent), which is listed in the Orange Book for Otezla®. Between March 1 and April 4, 2019, Celgene filed amended complaints against Hetero, MSN Laboratories Private Limited and Emcure for infringement of one or more of the above-listed patents. On October 1, 2019, Celgene filed an amended complaint against Mankind for infringement of the ’940, ’302, ’536, ’243 and ’330 Patents. On October 8, 2019, Celgene filed a separate lawsuit against Zydus Pharmaceuticals (USA) Inc. in the New Jersey District Court for infringement of U.S. Patent Nos. 8,093,283 (the ’283 Patent) and 8,629,173 (the ’173 Patent), which are not listed in the Orange Book for Otezla®. On December 19, 2019, the New Jersey District Court consolidated this lawsuit for discovery and case management purposes into the existing consolidated case, *Celgene Corp. v. Sandoz Inc., et al*. Each defendant has filed an answer to the above-listed complaints and amended complaints disputing infringement and/or validity of the patents asserted against it. Along with their answers, each of Alkem, Hetero, Cipla Ltd, DRL, Emcure, Glenmark, Macleods, Mankind, Pharmascience, Sandoz Inc., Shilpa, Actavis, Torrent, Unichem and Zydus Pharmaceuticals (USA) Inc. filed declaratory judgment counterclaims asserting that some or all of the patents are not infringed and/or are invalid. In August 2019, based on a joint request by Celgene and Glenmark, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, having made, using, selling, offering to sell, importing, or distributing of Glenmark’s apremilast product during the term of the ’940, ’638, ’302, ’101, ’536, ’243, ’330 and ’541 Patents, unless authorized pursuant to a confidential settlement agreement.

Following Amgen’s acquisition of the patents-in-suit and the new drug application for Otezla®, on February 14, 2020, the New Jersey District Court issued an order substituting Amgen for Celgene as plaintiff in the consolidated action and all related actions, terminating Celgene as plaintiff in the consolidated action and all related actions, and amending the case caption in the consolidated action and all related actions to reflect Amgen as the sole plaintiff.

On March 25, 2020, based on a joint request by Amgen and Unichem, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Unichem's apremilast product during the term of the '940, '638, '302, '101, '536, '243, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On April 3, 2020, based on a joint request by Amgen and Hetero, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Hetero's apremilast product during the term of the '940, '516, '638, '302, '101, '536, '717, '243, '330, '854 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On May 28, 2020, based on a joint request by Amgen and Emcure, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Emcure's apremilast product during the term of the '638, '101, '854 and '541 Patents unless authorized pursuant to a confidential settlement agreement. On July 7, 2020, the New Jersey District Court ordered a stipulated dismissal without prejudice of all claims, counterclaims, and affirmative defenses between Amgen and Sandoz Inc. with respect to the '717, '516 and '854 Patents, leaving the '940, '302, '536, '243, '330, '638, '101 and '541 Patents asserted by Amgen against Sandoz Inc. in the litigation. On August 6, 2020, based on a joint request by Amgen and Mankind, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Mankind's apremilast product during the term of the '940, '302, '536, '243, '330, '638, '101 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On August 14, 2020, based on a joint request by Amgen and Macleods, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Macleods' apremilast product during the term of the '638 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On October 7, 2020, based on a joint request by Amgen and Amneal Pharmaceuticals LLC, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Amneal Pharmaceuticals LLC's apremilast product during the term of the '101, '940, '638, '302, '536, '243, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On December 30, 2020, based on a joint request by Amgen and Shilpa, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Shilpa's apremilast product during the term of the '638, '101 and '854 Patents, unless authorized pursuant to a confidential settlement agreement. On January 26, 2021, based on a joint request by Amgen and Actavis, the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Actavis' apremilast product during the term of the '940, '516, '638, '302, '536, '717, '330, '854 and '541 Patents, unless authorized pursuant to a confidential settlement agreement.

Trial in the consolidated action against the remaining defendants is scheduled to commence on June 14, 2021.

Sensipar® (cinacalcet) ANDA Patent Litigation

Amgen Inc. v. Amneal Pharmaceuticals LLC, et al. (formerly, Amgen Inc. v. Aurobindo Pharma Ltd. et al.)

Beginning in September 2016, Amgen filed 14 separate lawsuits in the Delaware District Court for infringement of our U.S. Patent No. 9,375,405 (the '405 Patent) against a number of manufacturers of purported generic versions of our Sensipar® product. In February 2017, the Delaware District Court consolidated these 14 lawsuits into a single case, *Amgen Inc. v. Aurobindo Pharma Ltd. et al*. In June 2017, Amgen filed an additional lawsuit in the Delaware District Court for infringement of the '405 Patent which was consolidated into *Amgen Inc. v. Aurobindo Pharma Ltd. et al*. in August 2017. The '405 Patent is entitled "Rapid Dissolution Formulation of a Calcium Receptor-Active Compound" and expires in 2026. All defendants responding to the complaint denied infringement and sought judgment that the '405 Patent is invalid and/or not infringed.

Between September and November of 2017, Amgen filed, and the Delaware District Court signed, stipulated dismissals of the lawsuit against Micro Labs Ltd. and Micro Labs USA, Inc., and the lawsuit against Apotex, as well as consent judgments filed by Amgen and each of (1) Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, Sun); (2) Ajanta Pharma Limited and Ajanta Pharma USA, Inc.; (3) Hetero USA Inc., Hetero Labs Ltd. and Hetero Labs Ltd. Unit V; and (4) Breckenridge. Each consent judgment stipulated to an entry of judgment of infringement and validity of the '405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of or distribution into the United States of the respective defendant's cinacalcet product during the term of the '405 Patent, unless specifically authorized pursuant to the confidential settlement agreement.

In March 2018, the Delaware District Court commenced trial on the infringement claims and defenses in the *Amgen Inc. v. Aurobindo Pharma Ltd. et al.* consolidated lawsuit against the defendants that remained in the lawsuit, collectively consisting of (1) Watson Laboratories, Inc. and Actavis Pharma, Inc. (collectively, Watson); (2) Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); (3) Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, Zydus); and (4) Piramal Healthcare UK Limited (Piramal). Just prior to trial, the Delaware District Court signed consent judgments filed by Amgen and each of Cipla, and Strides Pharma Global Pte Limited and Strides Pharma, Inc. (collectively, Strides), and a consent judgment filed by Amgen and Aurobindo. In each consent judgment, the parties stipulated to an entry of judgment of infringement and validity of the '405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of or distribution into the United States of the applicable defendant's cinacalcet product during the term of the '405 Patent, unless specifically authorized pursuant to the applicable confidential settlement agreement. Just prior to trial, the Delaware District Court also entered orders dismissing each of DRL and Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan), on stipulations between Amgen and such parties, respectively, subject to the terms of confidential settlement agreements.

In July 2018, the Delaware District Court issued a trial order finding on the infringement claims and defenses in the *Amgen Inc. v. Aurobindo Pharma Ltd. et al.* consolidated lawsuit that Zydus infringes the '405 Patent and that Amneal, Piramal and Watson do not infringe the '405 Patent. In August 2018, the Delaware District Court issued an order dismissing, without prejudice, the invalidity counterclaims of Amneal, Piramal and Watson and entered judgment of noninfringement of the '405 Patent in favor of Amneal, Piramal and Watson. In September 2018, Amgen filed a notice of appeal to the Federal Circuit Court.

In October 2018, the Delaware District Court dismissed, without prejudice, the invalidity counterclaims of Zydus and entered judgment of infringement of the '405 Patent by Zydus in favor of Amgen, including an order that the effective date of the FDA approval of Zydus' generic version of Sensipar® shall be no earlier than the expiry date of our '405 Patent. Also in October 2018, Zydus filed a notice of appeal to the Federal Circuit Court, and the Federal Circuit Court consolidated the appeals of Zydus and Amgen.

In December 2018, the FDA approved Watson's generic version of Sensipar® and Watson's parent company, Teva Pharmaceutical Industries Ltd. (Teva), began selling its product at-risk notwithstanding that the appeals were pending at the Federal Circuit Court. On January 2, 2019, Amgen, Watson and Teva entered into a settlement agreement in which Teva agreed to stop selling its generic product until the mid-year 2021 (or earlier under certain circumstances) and to pay Amgen an undisclosed amount. On January 9, 2019, Watson and Amgen filed a motion asking the Delaware District Court to vacate its final judgment of noninfringement as to Watson and to enter a proposed consent judgment of infringement and validity of the '405 Patent and an injunction prohibiting the making, having made, using, selling, offering to sell, or distributing Watson's cinacalcet product in the United States or importing Watson's cinacalcet product into the United States, consistent with the confidential settlement agreement. On January 11, 2019, the Federal Circuit Court stayed the pending appeal by Amgen of the judgment of noninfringement as to Watson in order for the Delaware District Court to rule on the motion of Watson and Amgen. On March 26, 2019, the Delaware District Court denied the joint motion for indicative ruling of Watson and Amgen. On April 10, 2019, Amgen filed an appeal to the Federal Circuit Court and the Federal Circuit Court lifted the stay of Amgen's appeal of the judgment of noninfringement as to Watson and consolidated it with Amgen's appeal of the Delaware District Court's denial of the joint motion for indicative ruling. On September 13, 2019, the Federal Circuit Court denied Amgen's motion and lifted the stay of the briefing schedule which had been stayed pending disposition of Amgen's motion to vacate. On July 9, 2020, the Federal Circuit Court granted a motion filed by Amgen and Watson to dismiss Amgen's appeals of the Delaware District Court's judgment of noninfringement as to Watson and denial of the joint motion for indicative ruling.

On March 19, 2019, Amgen filed an emergency motion for an injunction pending appeal, seeking an order from the Delaware District Court enjoining defendant Piramal from making, using, selling, offering for sale or importing its generic cinacalcet product. Amgen's motion follows an announcement that Slate Run Pharmaceuticals LLC (Slate Run), in partnership with Piramal, had begun selling Piramal's generic cinacalcet product at-risk notwithstanding the appeals pending at the Federal Circuit Court. On April 15, 2019, the Delaware District Court signed an order enjoining Piramal and Slate Run from selling their generic cinacalcet product until certain events occur related to a decision by the Federal Circuit Court on the parties' appeal. The order has no effect on the product that Piramal and Slate Run had already sold to third parties.

On January 7, 2020, the Federal Circuit Court issued an opinion affirming the judgment of noninfringement with respect to Piramal, affirming the judgment of infringement with respect to Zydus and vacating and remanding to the Delaware District Court for further consideration the judgment of noninfringement with respect to Amneal. On April 22, 2020, the Federal Circuit Court issued a mandate returning the case to the Delaware District Court. On September 8, 2020, the Delaware District Court entered judgment of validity and infringement of the '405 Patent in the lawsuit filed against Amneal and, except to the extent specifically authorized in a confidential settlement agreement, enjoined Amneal from infringing the '405 Patent by making, using, selling, offering to sell or importing Amneal's cinacalcet product during the term of the patent.

A hearing before the Delaware District Court on the request of Piramal to recover damages for being enjoined during the pendency of Amgen's appeal has been rescheduled for March 24, 2021. On October 14, 2020, the Delaware District Court issued an order permitting Slate Run, Piramal's business partner, to intervene in the pending action.

ENBREL Patent Litigation

Immunex Corporation, et al. v. Sandoz Inc., et al.

In February 2016, two affiliates of Amgen Inc., Immunex Corporation and Amgen Manufacturing, Limited (collectively, Amgen), along with Hoffmann-La Roche Inc. (Roche), filed a lawsuit in the New Jersey District Court against Sandoz Inc., Sandoz International GmbH and Sandoz GmbH (collectively, Sandoz). This lawsuit stems from Sandoz's submission of an application for FDA licensure of an etanercept product as biosimilar to Amgen's ENBREL. Amgen and Roche have asserted infringement of five patents: U.S. Patent Nos. 8,063,182 (the '182 Patent), 8,163,522 (the '522 Patent), 7,915,225 (the '225 Patent), 8,119,605 (the '605 Patent) and 8,722,631 (the '631 Patent). By their complaint, Amgen and Roche seek an injunction to prohibit Sandoz from commercializing its biosimilar etanercept product in the United States prior to the expiry of such patents. All Sandoz defendants responded by denying infringement and/or asserting that the patents at issue are invalid. In August 2016, and subject to the terms of a confidential stipulation, the New Jersey District Court entered a preliminary injunction prohibiting Sandoz from making, using, importing, selling or offering for sale Sandoz's etanercept product. Sandoz's Erelzi™, a biosimilar to ENBREL, was approved by the FDA in August 2016.

In September 2018, the New Jersey District Court entered an order that the making, using, offering to sell or selling in the United States or the importation into the United States by Sandoz of Sandoz's biosimilar etanercept product infringes the '182 and '522 Patents and held a bench trial, focusing on Sandoz's challenges to the validity of these patents.

On August 9, 2019, the New Jersey District Court issued its decision upholding the validity of the '182 and '522 Patents. On October 8, 2019, by stipulation of Amgen and Sandoz, the New Jersey District Court entered final judgment and a permanent injunction prohibiting Sandoz from making, using, importing, selling or offering for sale Sandoz's etanercept product, and, on the same day, Sandoz appealed the final judgment to the Federal Circuit Court. Following a motion by Sandoz, the Federal Circuit Court ordered an expedited briefing schedule for the appeal.

On March 4, 2020, the Federal Circuit Court heard oral argument on the appeal. On July 1, 2020, the Federal Circuit Court affirmed the judgment of the New Jersey District Court upholding the validity of the '182 and '522 Patents. On September 29, 2020, the Federal Circuit Court denied the petition for rehearing of Sandoz filed on July 31, 2020. On January 29, 2021, Sandoz filed a petition for certiorari with the U.S. Supreme Court seeking review of the Federal Circuit Court's affirmance of the validity of the '182 and '522 Patents.

Immunex Corporation, et al. v. Samsung Bioepis Co., Ltd.

On April 30, 2019, two affiliates of Amgen Inc., Immunex Corporation and Amgen Manufacturing, Limited (collectively, Amgen), along with Roche, filed a lawsuit in the New Jersey District Court against Samsung Bioepis Co., Ltd. (Bioepis). This lawsuit stems from Bioepis' submission of an application for FDA licensure of an etanercept product as biosimilar to Amgen's ENBREL. Amgen and Roche have asserted infringement of five patents: the '182, '522, '225, '605 and '631 Patents. By their complaint, Amgen and Roche seek an injunction to prohibit Bioepis from commercializing its biosimilar etanercept product in the United States prior to the expiry of such patents. On August 5, 2019, Bioepis responded to the complaint, denying infringement and seeking judgment that the patents-in-suit are invalid, unenforceable and/or not infringed. On January 9, 2020 and subject to the terms of a confidential stipulation and court order of January 6, 2020, the New Jersey District Court entered a consent injunction that prohibits Bioepis from making, using, offering to sell, selling or importing into the United States Bioepis' etanercept product. Amgen and Bioepis entered into an agreement with respect to an injunction regarding etanercept as set out in the New Jersey District Court's order of January 6, 2020. On January 15, 2020, the New Jersey District Court entered an order administratively staying the case pursuant to a joint request of Amgen and Bioepis.

Repatha® Patent Litigation

Amgen Inc., et al. v. Sanofi, et al.

In October 2014, Amgen initiated a series of lawsuits that were consolidated by the Delaware District Court in December 2014 into a single case against Sanofi, Sanofi-Aventis U.S. LLC and Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc. (collectively, Sanofi) and Regeneron Pharmaceuticals, Inc. (Regeneron), addressing seven of our patents: U.S. Patent Nos. 8,563,698; 8,829,165 (the '165 Patent); 8,859,741 (the '741 Patent); 8,871,913; 8,871,914; 8,883,983; and 8,889,834. These patents describe and claim monoclonal antibodies to proprotein convertase subtilisin/kexin type 9 (PCSK9). By its complaints, Amgen seeks an injunction to prevent the infringing manufacture, use and sale of Sanofi and Regeneron's alirocumab, a monoclonal antibody targeting PCSK9. In January 2016, the Delaware District Court granted Amgen's motion to amend the complaint to add its affiliates, Amgen Manufacturing, Limited and Amgen USA Inc., as plaintiffs and to add the allegation that Sanofi and Regeneron's infringement of Amgen's patents is willful.

In February 2016, the Delaware District Court entered a stipulated order finding alirocumab and the drug product containing it, PRALUENT® infringe certain of Amgen's patents, including claims 2, 7, 9, 15, 19 and 29 of the '165 Patent and claim 7 of the '741 Patent. In March 2016, the Delaware District Court entered judgment in favor of Amgen following a five-day jury trial and a unanimous jury verdict that these patent claims are all valid. In January 2017, the Delaware District Court denied Sanofi and Regeneron's post-trial motions seeking a new trial and for judgment as a matter of law, and granted Amgen's motion for a permanent injunction prohibiting the infringing manufacture, use, sale, offer for sale or import of alirocumab in the United States. Sanofi and Regeneron filed an appeal of the judgment and the permanent injunction to the Federal Circuit Court. In February 2017, following a motion by Sanofi and Regeneron, the Federal Circuit Court entered a stay of the permanent injunction during the pendency of the appeal. In October 2017, the Federal Circuit Court reversed in part the judgment of the Delaware District Court and remanded for a new trial two of the patent validity defenses (lack of written description and enablement of the claimed inventions), and affirmed the Delaware District Court's judgment of infringement of claims 2, 7, 9, 15, 19 and 29 of the '165 Patent and claim 7 of the '741 Patent and the third patent validity defense (finding that the claimed inventions were not obvious to a person of ordinary skill in the field of the patents).

In March 2018, the Federal Circuit Court issued a mandate returning the case to the Delaware District Court for a new trial on two of Sanofi and Regeneron's challenges to the validity of our patents (lack of written description and enablement of the claimed inventions) and for further consideration of a permanent injunction. In July 2018, Amgen filed a petition for certiorari with the U.S. Supreme Court seeking review of the Federal Circuit Court's conclusion that the judgment affirming the validity of Amgen's patents was based, in part, on an erroneous application of the law of written description. On January 7, 2019, the U.S. Supreme Court denied Amgen's petition for certiorari. On remand, the Delaware District Court scheduled a new trial on Sanofi and Regeneron's challenges to the validity of our patents based on lack of written description and enablement of the claimed inventions. The Delaware District Court also entered judgment on the pleadings for Sanofi and Regeneron on Amgen's claim of willful infringement.

On February 25, 2019, a jury of the Delaware District Court unanimously upheld the validity of claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent. The jury also found that claims 7 and 15 of the '165 Patent meet the enablement requirement, but are invalid for failure to meet the written description requirement. On March 18, 2019, Sanofi and Regeneron filed post-trial motions seeking to reverse judgment as a matter of law or for a new trial with respect to claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent, and Amgen filed a motion for a permanent injunction. On June 6, 13 and 21, 2019, the Delaware District Court held evidentiary hearings on Amgen's motion for a permanent injunction against PRALUENT®. On August 28, 2019, the Delaware District Court ruled on the post-trial motions, denying Sanofi and Regeneron's request for a new trial and their request to reverse the jury verdict that the '165 Patent and the '741 Patent provide written description support for the claimed inventions. The Delaware District Court also ruled as a matter of law that claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent are invalid for failing to meet the enablement requirement, overturning the jury verdict. On October 23, 2019, Amgen filed a notice of appeal to the Federal Circuit Court. On December 9, 2020, the Federal Circuit Court heard oral argument on the appeal.

Patent Disputes in the International Region

We are involved in and expect future involvement in additional disputes regarding our PCSK9 patents in other jurisdictions and regions. This includes matters filed against us and that we have filed in the United Kingdom, Germany, France, the Netherlands, Italy, Spain and Japan.

In February 2016, the European Patent Office (EPO) granted European Patent No. 2,215,124 (EP 2,215,124) to Amgen. This patent describes and claims monoclonal antibodies to PCSK9 and methods of treatment and Sanofi filed an opposition to the patent in the EPO seeking to invalidate it. In November 2016, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A. and Sanofi Winthrop Industrie S.A. filed a joint opposition against Amgen's patent, and each of Eli Lilly and Company, Regeneron and Strawman Ltd. also filed oppositions to Amgen's patent. In November 2018, the EPO confirmed the validity of Amgen's EP 2,215,124, which was appealed to the Technical Board of Appeal (TBA). On October 29, 2020, the TBA upheld the validity of certain claims, including claims that protect Repatha®, but ruled that broader claims encompassing PRALUENT® were invalid. As a result of the TBA's decision, national litigations regarding PRALUENT® in Europe are in the process of being resolved.

On April 24, 2020, the Supreme Court of Japan declined to hear Sanofi K.K.'s appeals making final the Japanese High Court's decisions that PRALUENT® infringes Amgen's valid patent rights in Japan. On June 24, 2020, Amgen filed written answers to the invalidity trials initiated by Regeneron on February 12, 2020 before the Japan Patent Office seeking to invalidate Amgen's Japanese patents that were previously held infringed by PRALUENT® and valid over challenges filed by Sanofi K.K. Damages proceedings against Sanofi K.K. are ongoing before the Tokyo District Court, where Sanofi K.K. has initiated new validity challenges to Amgen patents in Japan.

NEUPOGEN® (filgrastim)/Neulasta® Patent Litigation

Amgen Inc., et al. v. Pfizer Inc. et al.

In July 2018, Amgen Inc. and its wholly owned subsidiary, Amgen Manufacturing, Limited (collectively, Amgen), filed a lawsuit in the Delaware District Court against Pfizer Inc. and Hospira Inc. (collectively, Pfizer). This lawsuit stems from Pfizer's submission of an application for FDA licensure of a filgrastim product as biosimilar to Amgen's NEUPOGEN®. Amgen has asserted infringement of U.S. Patent No. 9,643,997 (the '997 Patent) and seeks, among other remedies, injunctive relief to prohibit Pfizer from infringing the '997 Patent. In July 2018, the FDA approved Pfizer's NIVESTYM™, a biosimilar to NEUPOGEN®, which was subsequently launched in October 2018. In August 2018, Pfizer answered the complaint and counterclaimed seeking a declaration that Pfizer does not infringe Amgen's '997 Patent and that the patent is invalid.

On March 22, 2019, Amgen filed an amended complaint against Pfizer in the Delaware District Court narrowing the patent claims at issue in the infringement dispute and adding a request for damages. On April 11, 2019, Pfizer answered Amgen's amended complaint including counterclaims seeking declaratory judgments of noninfringement and invalidity. On February 18, 2020, the Delaware District Court entered an amended scheduling order moving the trial on the infringement of our '997 Patent to May 17, 2021, to enable Amgen to seek additional discovery into Pfizer's invalidity defenses.

On April 24, 2020, Amgen filed a separate lawsuit in the Delaware District Court against Pfizer for infringement of U.S. Patent No. 10,577,392 (the '392 Patent) and seeks, among other remedies, damages and injunctive relief to prohibit Pfizer from infringing the '392 Patent by the manufacture, import and sale of Pfizer's NIVESTYM™. On January 7, 2021, the Delaware District Court granted Pfizer's request to stay the patent infringement lawsuit on the '392 Patent until the co-pending patent infringement lawsuit on the '997 Patent is resolved.

Amgen Inc., et al. v. Hospira Inc. et al.

On February 11, 2020, Amgen Inc. and its wholly owned subsidiary, Amgen Manufacturing, Limited (collectively, Amgen), filed a lawsuit in the Delaware District Court against Pfizer. This lawsuit stems from Pfizer's submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen's Neulasta®. Amgen has asserted infringement of U.S. Patent No. 8,273,707 (the '707 Patent) and seeks, among other remedies, injunctive relief to prohibit Pfizer from infringing the '707 Patent. On March 4, 2020, Pfizer filed a motion requesting the Delaware District Court to dismiss the complaint by Amgen alleging noninfringement of the '707 Patent. In June 2020, the FDA approved Pfizer's NYVEPRIA™, a biosimilar to Amgen's Neulasta®.

Patent Trial and Appeal Board (PTAB) Challenge

Lupin PTAB Challenge

On December 15, 2020, Lupin Limited (Lupin) filed a petition to institute inter parties review (IPR) proceeding at the U.S. Patent and Trademark Office (USPTO) of U.S. Patent No. 9,856,287 (the '287 Patent) challenging claims of the '287 Patent as unpatentable. Amgen' s preliminary response is due on April 14, 2021 and the PTAB will then have no more than three months to decide whether to institute a proceeding.

Apotex PTAB Challenge

In February 2017, the PTAB of the USPTO granted Apotex's petition to institute IPR proceeding of U.S. Patent No. 8,952,138 (the '138 Patent), challenging claims of the '138 Patent as unpatentable. In May 2017, Amgen filed its response. In February 2018, the PTAB issued a final decision holding all but one claim of the '138 Patent as unpatentable and Apotex filed a request for rehearing in March 2018.

On May 20, 2019, the PTAB issued a decision denying Apotex's request for rehearing on the PTAB's finding and *sua sponte* amending the final decision with a finding that the one remaining claim in Amgen's '138 Patent is unpatentable. On July 22, 2019, Amgen filed a notice of appeal to the Federal Circuit Court with respect to all claims held to be unpatentable. On August 5, 2019, Apotex provided notice that it would not participate in the appeal. On September 16, 2019, the USPTO filed a notice of intervention on the appeal. On March 24, 2020, the Federal Circuit Court vacated the decision by the PTAB and remanded the case to the PTAB for proceeding consistent with the Federal Circuit Court's decision in *Arthrex Inc. v. Smith & Nephew, Inc*., 941 F.3d 1320 (Fed. Cir. 2019).

On July 14, 2020, Amgen and Apotex filed a joint motion to terminate the IPR proceedings stating that there is no current dispute between the parties with respect to the '138 Patent. On July 29, 2020, the U.S. government filed a petition for writ of certiorari with respect to the cases that the Federal Circuit Court remanded to the PTAB, including the case regarding the '138 Patent, for proceedings consistent with its decision in *Arthrex Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), requesting that such remanded cases be held pending the U.S. Supreme Court's disposition of the petition for writ of certiorari in *United States v. Arthrex, Inc*., No. 19-1434. On August 25, 2020, Amgen filed its response to the U.S. government's petition for writ of certiorari indicating that Amgen did not intend to respond unless requested by the U.S. Supreme Court.

Breach of Contract Action

Novartis Pharma AG v. Amgen Inc.

On April 4, 2019, Amgen filed a lawsuit in the U.S. District Court for the Southern District of New York (the New York Southern District Court) against Novartis Pharma AG (Novartis) seeking a declaratory judgment that Novartis materially breached two collaboration agreements Amgen and Novartis entered into in 2015 and 2017 (the 2015 Agreement and the 2017 Agreement, respectively) related to the development and commercialization of Aimovig ® due to Novartis' affiliate Sandoz GmbH entering into a contract manufacturing agreement with Alder BioPharmaceuticals, Inc. (Alder) related to eptinezumab, an expected direct competitor to Aimovig® and entrant in the calcitonin gene-related peptide (CGRP)-related migraine therapy market. Amgen seeks to terminate its collaboration agreements with Novartis and also seeks damages from Novartis for breach of contract and negligent misrepresentation. Also on April 4, 2019, Novartis initiated a separate lawsuit against Amgen in the same court seeking declaratory judgment that Novartis, alternatively, did not materially breach the collaboration agreements or, even if it did breach the collaboration agreements, such breach was not material and has been cured, and that Amgen may not terminate the collaboration agreements. On April 8, 2019, Amgen answered Novartis' complaint and filed counterclaims seeking a declaratory judgment that Novartis materially breached the collaboration agreements due to its affiliate Sandoz GmbH entering into the contract manufacturing agreement with Alder. In its counterclaim, Amgen seeks to terminate its collaboration agreements with Novartis and also seeks damages from Novartis for breach of contract and negligent misrepresentation. On July 16, 2019, Novartis filed an amended complaint adding a claim for breach of contract alleging Novartis is owed amounts associated with 2018 budget overruns and Amgen responded with a counterclaim alleging additional breaches by Novartis of the collaboration agreements. On September 17, 2019 and October 8, 2019, Novartis and Amgen, respectively, each filed its motion for judgment on the pleadings. On February 3, 2020, Amgen was granted leave to file its amended counterclaims. On February 4, 2020, Amgen filed its amended answer to Novartis' first amended complaint and second amended counterclaims for affirmative relief to add a fraudulent inducement claim. On February 18, 2020, Novartis filed its answer and affirmative defenses to Amgen's second amended counterclaims.

On June 9, 2020, the New York Southern District Court entered an order granting Novartis' motion for judgment on the pleadings that Novartis did not breach the 2017 Agreement, and denying Amgen's motions for judgment on the pleadings seeking dismissal of Novartis' amended complaint that Novartis did not breach the 2015 Agreement or the 2017 Agreement, and Novartis timely cured any breach. On June 23, 2020, Amgen filed a motion for clarification and/or reconsideration of the June 9, 2020 order, which was denied on September 14, 2020.

Antitrust Class Action

Sensipar® Antitrust Class Actions

From February to April 2019, four plaintiffs filed putative class action lawsuits against Amgen and various entities affiliated with Teva alleging anticompetitive conduct in connection with settlements between Amgen and manufacturers of generic cinacalcet product. Two of those actions were brought in the Delaware District Court, captioned *UFCW Local 1500 Welfare Fund v. Amgen Inc., et al.* (February 21, 2019) (Local 1500) and *Cesar Castillo, Inc. v. Amgen Inc., et al.* (February 26, 2019) (Castillo). The third action was brought in the New Jersey District Court, captioned *Teamsters Local 237 Welfare Fund, et al. v. Amgen Inc., et al.* (March 14, 2019) (Local 237) and the fourth action was brought in the U.S. District Court for the Eastern District of Pennsylvania (the Eastern Pennsylvania District Court), captioned *KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. v. Amgen Inc., et al* (April 10, 2019) (KPH). Each of the lawsuits is brought on behalf of a putative class of direct or indirect purchasers of Sensipar® and alleges that the plaintiffs have overpaid for Sensipar® as a result of Amgen's conduct that allegedly improperly delayed market entry by manufacturers of generic cinacalcet products. The lawsuits focus predominantly on the settlement among Amgen, Watson and Teva of the parties' patent infringement litigation. Each of the lawsuits seeks, among other things, treble damages, equitable relief and attorneys' fees and costs. On April 10, 2019, the plaintiff in the KPH lawsuit filed a motion seeking to have the four lawsuits consolidated and designated as a multidistrict litigation (MDL) in the Eastern Pennsylvania District Court, and the plaintiff in the Local 1500 lawsuit filed a motion seeking to have the four lawsuits, along with *Cipla Ltd. v. Amgen Inc.*, consolidated and designated as a MDL in the Delaware District Court.

On July 31, 2019, the MDL panel entered an order consolidating in the Delaware District Court the four class action lawsuits. On September 13, 2019, the plaintiffs filed amended complaints, and on October 15, 2019, Amgen filed its motion to dismiss both the direct purchaser plaintiffs' consolidated class action complaint and the indirect purchaser end payor plaintiffs' complaint. On December 6, 2019, the plaintiffs responded to Amgen's motion to dismiss and, on January 10, 2020, Amgen filed its response. On February 6, 2020, the motions in the class action lawsuits were transferred to the U.S. Magistrate Judge for the District of Delaware (Magistrate Judge) for a recommendation. The MDL panel certified its conditional transfer order on February 6, 2020 transferring the additional class action lawsuit brought in the U.S. District Court for the Southern District of Florida, captioned *MSP Recovery Claims v. Amgen Inc., et al.*, to the Delaware District Court.

On July 22, 2020, the Magistrate Judge issued a recommendation to the Delaware District Court that the claims against Amgen be dismissed but leave be given to plaintiffs to amend their complaints. On August 5, 2020, the plaintiffs filed objections to the Magistrate Judge's report and recommendation. On August 19, 2020, Amgen filed a response to the plaintiffs' objections. On November 30, 2020, the District Court adopted the Magistrate Judge's recommendation in part and denied it in part, denying Amgen's motion to dismiss on the grounds that plaintiffs adequately alleged reverse payment claims but granted Amgen's motion to dismiss with respect to the other Federal antitrust claims. On December 23, 2020, Teva, Watson and Actavis filed a motion for interlocutory appeal and for a stay pending appeal and Amgen filed its joinder (the 1292 Motion). On January 5, 2021, a joint status report was filed advising the Delaware District Court that the defendants are still considering whether to withdraw the 1292 Motion and plaintiffs' offer to stay discovery, pending further rulings on motions to dismiss the amended complaints. On January 19, 2021, a joint status report was filed pursuant to the Delaware District Court's January 6, 2021 order along with a stipulation to defer the 1292 Motion until after rulings on the amended complaints.

Humira® Biosimilar Antitrust Class Actions

From March to May 2019, twelve purported class actions against Amgen, along with AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively, AbbVie), were filed in the U.S. District Court for the Northern District of Illinois (the Illinois Northern District Court). The cases are captioned: *UFCW Local 1500 Welfare Fund v. AbbVie Inc., et al.* (March 18, 2019) (Local 1500); *Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund v. AbbVie Inc., et al.* (March 20, 2019); *Mayor and City Council of Baltimore v. AbbVie Inc., et al.* (March 22, 2019); *Pipe Trades Services MN Welfare Fund v. AbbVie Inc., et al.* (March 29, 2019); *St. Paul Electrical Workers' Health Plan v. AbbVie Inc., et al.* (March 29, 2019); *Welfare Plan of the International Union of Operating Engineers Locals 137, 137A, 137B, 137C and 137R v. AbbVie Inc., et al.* (April 1, 2019); *Law Enforcement Health Benefits, Inc. v. AbbVie, Inc., et al.* (April 9, 2019) (Law Enforcement); *Kentucky Laborers District Council Health and Welfare Fund v. AbbVie, Inc., et al.* (April 16, 2019); *Sheet Metal Workers' Local Union No. 28 Welfare Fund v. AbbVie, Inc., et al.* (April 19, 2019) (Sheet Metal Workers'); *Locals 302 & 612 of The International Union of Operating Engineers-Employers Construction Industry Health And Security Trust Fund v. AbbVie Inc., et al.* (April 25, 2019) (Construction Industry); *Louisiana Health Service & Indemnity Co., d/b/a Blue Cross and Blue Shield of Louisiana and HMO Louisiana, Inc. v. AbbVie Inc., et al.* (April 30, 2019) (Louisiana Health); and *Cleveland Bakers and Teamsters Health and Welfare Fund v. AbbVie Inc., et al.* (May 10, 2019) (Cleveland Bakers) (collectively, Humira® Antitrust Class Actions).

In each of the Humira® Antitrust Class Actions, the plaintiffs bring federal antitrust claims along with various state law claims under common law and antitrust, consumer protection and unfair competition statutes. In each case, the plaintiffs specifically allege that AbbVie has unlawfully monopolized the alleged market for Humira® and biosimilars of Humira®, including by creating an allegedly unlawful so-called patent thicket around Humira®. In the Local 1500, Sheet Metal Workers' and Construction Industry cases, the plaintiffs further allege that AbbVie entered into allegedly unlawful market division agreements with Amgen and other companies that had developed Humira® biosimilars, including Bioepis, Mylan, Sandoz, Inc., Fresenius Kabi USA, LLC, Pfizer Inc. and Momenta Pharmaceuticals, Inc., in connection with the settlement of patent litigation relating to Humira®, whereby Amgen and the other defendants that have developed Humira® biosimilars were permitted to market those products in Europe as early as October 2018, while remaining off the market in the United States until 2023. In each of the Humira® Antitrust Class Actions other than the Local 1500 and Construction Industry cases, the plaintiffs allege that AbbVie and Amgen entered into an allegedly unlawful settlement agreement under which Amgen allegedly agreed to delay its entry into the U.S. market with AMGEVITA ™(adalimumab), its Humira® biosimilar, in exchange for an alleged promise of exclusivity as the sole Humira® biosimilar in that market for five months, beginning in January 2023. In each of the Humira® Antitrust Class Actions, plaintiffs seek injunctive relief, treble damages and attorney's fees on behalf of a putative class of third-party payers and/or consumers that have indirectly purchased, paid for or provided reimbursement for Humira® in the United States. Defendants' responses to the first six complaints were stayed by the court. On June 4, 2019, the Illinois Northern District Court entered an order consolidating the twelve purported class action cases for pre-trial purposes.

On August 9, 2019, the plaintiffs filed their consolidated complaint, naming as defendants Amgen, along with AbbVie, Bioepis, Sandoz, Inc. and Fresenius Kabi USA LLC. On October 11, 2019, the defendants filed a joint motion to dismiss the consolidated complaint (as well as brief individual motions), challenging the legal sufficiency of the plaintiffs' allegations to state any claim for relief under the law. On November 19, 2019, plaintiffs filed their opposition to the motion to dismiss. On December 20, 2019, defendants filed their reply in support of the motion to dismiss. On June 8, 2020, the Illinois Northern District Court issued an order granting the motion by the defendants to dismiss the consolidated class action complaint. On June 29, 2020, the plaintiffs filed a status report asking the Illinois Northern District Court to convert the dismissal to one with prejudice. On June 30, 2020, the Illinois Northern District Court granted the motion. On July 28, 2020, the plaintiffs filed a notice of appeal. On October 5, 2020, the plaintiffs-appellants filed their opening brief to the U.S. Court of Appeals for the Seventh Circuit. Plaintiffs-appellants amicus briefs were filed in October 2020, including one by the Federal Trade Commission and one on behalf of 20 states, each filed on October 13, 2020. On December 21, 2020, the defendants-appellees filed their opposition brief. Defendants-appellees amicus briefs, including one by the Department of Justice, were filed on December 28, 2020. The plaintiffs-appellants' reply brief was filed on February 1, 2021, and oral argument has been scheduled for February 25, 2021.

Commitments – U.S. repatriation tax

Under the 2017 Tax Act, we elected to pay in eight annual installments the repatriation tax related primarily to prior indefinitely invested earnings of our foreign operations. The following table summarizes the remaining scheduled repatriation tax payments as of December 31, 2020 (in millions):

	Amounts
2021	$ 587
2022	587
2023	1,100
2024	1,467
2025	1,834
Total remaining U.S. repatriation tax commitments	$ 5,575

20. Quarterly financial data (unaudited)

The following tables summarize the Company's unaudited financial data on a quarterly basis. The sum of the quarterly earnings per-share amounts may not equal the amount reported for the full year because per-share amounts are computed independently for each quarter and for the full year based on respective weighted-average shares outstanding and dilutive securities.

Quarterly financial data is summarized as follows (in millions, except per-share data):

	2020 Quarters ended			
	December 31	September 30	June 30	March 31
Product sales	$ 6,334	$ 6,104	$ 5,908	$ 5,894
Gross profit from product sales	$ 4,737	$ 4,543	$ 4,420	$ 4,381
Net income	$ 1,615	$ 2,021	$ 1,803	$ 1,825
Earnings per share:				
Basic	$ 2.78	$ 3.45	$ 3.07	$ 3.09
Diluted	$ 2.76	$ 3.43	$ 3.05	$ 3.07

	2019 Quarters ended			
	December 31	September 30	June 30	March 31
Product sales	$ 5,881	$ 5,463	$ 5,574	$ 5,286
Gross profit from product sales	$ 4,628	$ 4,427	$ 4,562	$ 4,231
Net income	$ 1,703	$ 1,968	$ 2,179	$ 1,992
Earnings per share:				
Basic	$ 2.87	$ 3.29	$ 3.59	$ 3.20
Diluted	$ 2.85	$ 3.27	$ 3.57	$ 3.18

SCHEDULE II

AMGEN INC.

VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2020, 2019 and 2018

(In millions)

Allowance for doubtful accounts	Balance at beginning of period	Additions charged to costs and expenses	Other additions	Deductions	Balance at end of period
Year ended December 31, 2020	$ 26	$ 8	$ —	$ 2	$ 32
Year ended December 31, 2019	$ 48	$ —	$ —	$ 22	$ 26
Year ended December 31, 2018	$ 51	$ 1	$ —	$ 4	$ 48