AMGEN INC
Form 10-K
February 13, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K
(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission file number 001-37702
Amgen Inc.
(Exact name of registrant as specified in its charter)

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

(805) 447-1000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common stock, $0.0001 par value	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ý 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 ý
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 ý No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company ¨

(Do not check if a smaller reporting company)

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

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $125,649,811,435 as of June 30, 2017.(A)

(A) Excludes 1,188,740 shares of common stock held by directors and executive officers, and any stockholders whose ownership exceeds ten percent of the shares outstanding, at June 30, 2017. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

720,562,246

(Number of shares of common stock outstanding as of February 9, 2018)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2018 Annual Meeting of stockholders to be held May 22, 2018, are incorporated by reference into Part III of this annual report.

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PART I

Item 1. BUSINESS

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

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

Our strategy is to develop innovative medicines in six focused therapeutic areas that meet important unmet medical needs in addressing serious illness. We have a presence in approximately 100 countries worldwide with a primary focus in: oncology/hematology, cardiovascular disease, inflammation, bone health, nephrology and neuroscience. Amgen was incorporated in California in 1980 and became a Delaware corporation in 1987. Amgen operates in one business segment: human therapeutics.

Significant Developments

Following is a summary of significant developments affecting our business that have occurred and that we have reported since the filing of our Annual Report on Form 10-K for the year ended December 31, 2016, and in early 2018.

Products/Pipeline

Bone health

Prolia® (denosumab)

- In October 2017, we announced that the U.S. Food and Drug Administration (FDA) accepted for review the supplemental Biologics License Application (sBLA) for Prolia® for the treatment of patients with glucocorticoid-induced osteoporosis. The sBLA is based on a phase 3 study evaluating the safety and efficacy of Prolia® compared with risedronate in patients receiving glucocorticoid treatment. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of May 28, 2018.

XGEVA® (denosumab)

- In April 2017, we announced the submission of an application for a variation to the marketing authorization to the European Medicines Agency (EMA) for XGEVA®. The submission to the regulatory authority seeks to expand the currently approved XGEVA® indication for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors to include patients with multiple myeloma.
- In January 2018, we announced that the FDA approved the sBLA for XGEVA® to expand the currently approved indication for the prevention of SREs in patients with bone metastases from solid tumors to include patients with multiple myeloma.
- In February 2018, we announced that a phase 3 study of XGEVA® for a potential new indication as adjuvant treatment for women with high-risk, early stage breast cancer receiving standard of care neoadjuvant or adjuvant cancer therapy did not meet its primary endpoint of bone metastasis-free survival.

EVENITY™ (romosozumab)*

- In May 2017, we and UCB, our global collaboration partner in the development of EVENITY,™ announced that the EVENITY™ ARCH (Active-contRolled FraCture Study in Postmenopausal Women with Osteoporosis at High Risk of Fracture) study met both primary endpoints and the key secondary endpoint. An imbalance in positively adjudicated cardiovascular serious adverse events was observed in the study as a new safety signal.
- In July 2017, we and UCB announced that the FDA issued a Complete Response Letter for the Biologics License Application (BLA) for EVENITY™ as a treatment for postmenopausal women with osteoporosis. We intend to provide a resubmission, which will include data from the phase 3 ARCH study and select data from the phase 3 BRIDGE (PlaceBo-contRolled Study EvaluatIng the Efficacy anD Safety of Romosozumab in TreatinG mEn with Osteoporosis) study evaluating EVENITY™ in men with osteoporosis, in addition to the phase 3 FRAME (FRActure study in postmenopausal

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woMen with ostEoporosis) study. We are currently evaluating all EVENITY™ data and will be working in close collaboration with the FDA.

- In January 2018, we and UCB announced that the EMA accepted the Marketing Authorization Application (MAA) for EVENITY™ for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture.

Cardiovascular

Repatha® (evolocumab)

- In February 2017, we announced that the European Commission (EC) adopted a decision to change the Repatha® marketing authorization, approving a new single-dose, monthly delivery option. The new automated mini-doser with a pre-filled cartridge is a hands-free device that provides 420 mg of Repatha® in a single injection per administration.
- In March 2017, we announced that the phase 3 study evaluating Repatha® in patients who were receiving apheresis to reduce low-density lipoprotein cholesterol (LDL-C) met its primary endpoint.
- In June 2017, we announced the submission of an application for a variation to the marketing authorization to the EMA for Repatha®. The regulatory submission is based on the Repatha® cardiovascular outcomes study, FOURIER (Further Cardiovascular OUtcomes Research with Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibition in Subjects with Elevated Risk).
- In October 2017, the U.S. Court of Appeals for the Federal Circuit issued a ruling that reversed in part the decision of the U.S. District Court for the District of Delaware that had prohibited Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc., and Regeneron Pharmaceuticals, Inc. from infringing two patents that we hold for Repatha® by manufacturing, using, selling, offering for sale or importing alirocumab in the United States. See Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.
- In October 2017, we announced that a phase 3 study of Repatha® on top of maximally tolerated statin therapy in type 2 diabetic patients with hypercholesterolemia met its co-primary endpoints of the percent reduction from baseline in LDL-C at week 12 and the mean percent reduction from baseline in LDL-C at weeks 10 and 12. No new safety findings were identified.
- In December 2017, we announced that following priority review of our sBLA, the FDA approved Repatha® as the first PCSK9 inhibitor to prevent heart attacks, strokes and coronary revascularizations in adults with established cardiovascular disease based on data from the Repatha® cardiovascular outcomes study. The FDA also approved Repatha® to be used as an adjunct to diet, alone or in combination with other lipid-lowering therapies, such as statins, for the treatment of adults with primary hyperlipidemia to lower LDL-C. The new label also included data from the Repatha® cognitive function study showing Repatha® was non-inferior to placebo on selected cognitive function domains as assessed with the use of neuropsychological function tests over a median follow-up of 19 months.

Neuroscience

Aimovig™ (erenumab)*

- In April 2017, we announced an expanded collaboration with Novartis AG (Novartis) for Aimovig,™ which is being investigated for the prevention of migraine. As part of the expanded collaboration, Amgen and Novartis agreed to combine capabilities to co-commercialize Aimovig™ in the United States.
- In July 2017, we announced that the FDA accepted for review the BLA for Aimovig™ for the prevention of migraine in patients experiencing four or more migraine days per month. The FDA has set a PDUFA target action date of May 17, 2018.
- In January 2018, a phase 3b study met its primary endpoint and all secondary endpoints in patients with episodic migraine who had experienced two to four previous preventive treatment failures due to lack of efficacy or intolerable side effects.

Oncology/Hematology

Aranesp® (darbepoetin alfa)

- In October 2017, we announced that after a recommendation by the data safety monitoring committee, a phase 3 post-marketing requirement study to evaluate the safety and efficacy of Aranesp® in anemic patients with advanced non-small cell lung cancer receiving multi-cycle chemotherapy was terminated early. The study successfully met its primary endpoint of non-inferiority in overall survival compared to placebo, with no new safety findings.

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BLINCYTO® (blinatumomab)

- In July 2017, we announced that the FDA approved the sBLA for BLINCYTO® to include overall survival data from the phase 3 TOWER study. The approval converted BLINCYTO®'s accelerated approval to a full approval. The approval expanded the indication of BLINCYTO® for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.
- In December 2017, we announced that the FDA accepted for priority review the sBLA for the treatment of minimal residual disease in patients with ALL. The FDA has set a PDUFA target action date of March 29, 2018.
- In February 2018, we announced that the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion recommending a label variation for BLINCYTO® to include overall survival data from the phase 3 TOWER study supporting the conversion of the conditional marketing authorization to a full marketing authorization in adult patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL.

KYPROLIS® (carfilzomib)

- In July 2017, we announced positive results from the final analysis of the phase 3 ASPIRE (CArfilzomib, Lenalidomide, and DexamethaSone versus Lenalidomide and Dexamethasone for the treatment of PatIents with Relapsed Multiple MyEloma) study. The study met the key secondary endpoint of overall survival, demonstrating that KYPROLIS®, lenalidomide and dexamethasone reduced the risk of death by 21% over lenalidomide and dexamethasone alone.
- In October 2017, we announced top-line results of the phase 3 ARROW (RAndomized, Open-label, Phase 3 Study in Subjects with Relapsed and Refractory Multiple Myeloma Receiving Carfilzomib in Combination with Dexamethasone, Comparing Once-Weekly versus Twice-weekly Carfilzomib Dosing) study, which showed KYPROLIS® administered once-weekly at the 70 mg/m^2 dose with dexamethasone allowed relapsed and refractory multiple myeloma patients to live 3.6 months longer without their disease worsening than KYPROLIS® administered twice-weekly at the 27 mg/m^2 dose with dexamethasone. The overall safety profile of the once-weekly KYPROLIS® regimen was comparable to that of the twice-weekly regimen.
- In December 2017, we submitted a supplemental New Drug Application (sNDA) to the FDA and a variation to the Marketing Authorization to the EMA to include the overall survival data from the ASPIRE study in the product label.
- In January 2018, we announced that the FDA approved the sNDA to add overall survival data from the phase 3 head-to-head ENDEAVOR study to the prescribing information for KYPROLIS®.
- In January 2018, we announced that the CHMP of the EMA adopted a positive opinion recommending a label variation for KYPROLIS® to include updated overall survival data from the phase 3 head-to-head ENDEAVOR (RandomizEd, OpeN Label, Phase 3 Study of Carfilzomib Plus DExamethAsone Vs Bortezomib Plus DexamethasOne in Patients With Relapsed Multiple Myeloma) study in patients with relapsed or refractory multiple myeloma. The ENDEAVOR study demonstrated that KYPROLIS® and dexamethasone reduced the risk of death by 21 percent, and increased overall survival by 7.6 months versus VELCADE® (bortezomib) and dexamethasone.

Vectibix® (panitumumab)

- In June 2017, we announced that the FDA approved the sBLA for Vectibix® to more precisely define patients with wild-type RAS metastatic colorectal cancer, as first-line therapy in combination with FOLFOX and as monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin and irinotecan-containing chemotherapy.

Nephrology

Sensipar®/Mimpara® (cinacalcet)

- In August 2017, we announced that the EC granted Marketing Authorization of a pediatric formulation (granules in capsule for opening) of Mimpara® for the treatment of secondary hyperparathyroidism (sHPT) in children aged three years and older with end-stage renal disease on maintenance dialysis therapy in whom sHPT is not adequately controlled with standard of care therapy.

Biosimilars

AMJEVITA™ (adalimumab-atto) / AMGEVITA™ (biosimilar adalimumab)

- In March 2017, we announced that the EC granted market authorization for AMGEVITA™, a biosimilar to AbbVie's HUMIRA®, in all available indications.
- In September 2017, we announced that we have reached a global settlement with AbbVie to resolve all pending litigation regarding AMJEVITA™/AMGEVITA™. Under terms of the agreement, AbbVie will grant patent licenses for the use and sale of AMJEVITA™/AMGEVITA™ worldwide, on a country-by-country basis, and the companies have agreed to dismiss all pending patent litigation. We expect to launch AMGEVITA™ in Europe in October 2018 and AMJEVITA™ in the United States in January 2023.

ABP 980

- In March 2017, we announced the submission of a MAA to the EMA for ABP 980, a biosimilar candidate to Herceptin® (trastuzumab). ABP 980 is being developed in collaboration with Allergan plc (Allergan).
- In October 2017, we announced that the FDA accepted for review a BLA for ABP 980. The FDA has set a Biosimilar User Fee Act target action date of May 28, 2018.

MVASI™ (bevacizumab-awwb)

- In September 2017, we announced that the FDA approved MVASI™ for all eligible indications of the reference product, Avastin®. MVASI™ is the first anti-cancer biosimilar, as well as the first bevacizumab biosimilar, approved by the FDA. MVASI™ is approved for the treatment of five types of cancer. MVASI™ is being developed in collaboration with Allergan.
- In January 2018, we announced that the EC granted marketing authorization for MVASI™ (biosimilar bevacizumab) for the treatment of certain types of cancers.

Next-generation biomanufacturing

- In May 2017, our next-generation biomanufacturing plant in Singapore was approved by the FDA for certain commercial production.

2017 U.S. Tax Reform

- On December 22, 2017, the United States enacted major tax reform legislation, Public Law No. 115-97, commonly referred to as the Tax Cuts and Jobs Act (2017 Tax Act). The 2017 Tax Act imposes a repatriation tax on accumulated earnings of foreign subsidiaries, implements a territorial tax system together with a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. See Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

Offer to Purchase Common Stock

- On February 5, 2018, we announced a tender offer to purchase up to $10 billion of our common stock at a price not greater than $200 per share nor less than $175 per share. The tender is based on our confidence in the long-term outlook for our business, enhanced by the 2017 Tax Act, and is consistent with our ongoing objective to return capital to our stockholders. The tender offer expires at 12:00 Midnight, New York City time, at the end of Monday, March 5, 2018, unless the offer is extended.

* FDA provisionally approved trade name

Marketing, Distribution and Selected Marketed Products

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

In the United States, we sell primarily to pharmaceutical wholesale distributors that are the principal means of distributing our products to healthcare providers. We also market certain products directly to consumers through several direct-to-consumer channels, including print, television and online media, as well as through multi-channel

marketing. For further discussion, see

Government Regulation—Regulation of Product Marketing and Promotion. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country.

Our product sales to three large wholesalers, AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc., each individually accounted for more than 10% of total revenues for each of the years ended December 31, 2017, 2016 and 2015. On a combined basis, these wholesalers accounted for 96%, 96% and 97% of our U.S. gross product sales, for each of the years ended December 31, 2017, 2016 and 2015, respectively, and 81% of worldwide gross revenues for each of these years. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

For financial information related to our one business segment, see Part IV—Consolidated Statements of Income, Consolidated Balance Sheets, and Note 19, Segment information, to the Consolidated Financial Statements.

Our products are marketed around the world with the United States being our largest market. The following chart shows our product sales by principal product and by geography for the years ended 2017, 2016 and 2015.

Enbrel® (etanercept)

We market ENBREL primarily in the United States. It was launched in 1998 and is used primarily in indications for the treatment of adult patients with the following conditions:

- moderately to severely active rheumatoid arthritis,
- chronic moderate-to-severe plaque psoriasis patients who are candidates for systemic therapy or phototherapy, and
- active psoriatic arthritis.

Neulasta® (pegfilgrastim)

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

Aranesp® (darbepoetin alfa)

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

Aranesp® and EPOGEN® compete with each other in the United States, primarily in the dialysis setting.

Prolia® (denosumab)

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

Sensipar®/Mimpara® (cinacalcet)

We market cinacalcet as Sensipar® primarily in the United States and as Mimpara® primarily in Europe. It was launched in 2004 and is used primarily in the indication for the treatment of sHPT in adult patients with CKD who are on dialysis.

XGEVA® (denosumab)

We market XGEVA® primarily in the United States and Europe. XGEVA® was launched in the United States in 2010, and is used primarily in the indication for the prevention of SREs (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumors, including multiple myeloma. XGEVA® was launched in Europe in 2011, and is used primarily in the indication for the prevention of SREs in patients with bone metastases from solid tumors, and was recently approved for the prevention of SREs in patients with multiple myeloma.

EPOGEN® (epoetin alfa)

We market EPOGEN® in the United States for dialysis patients. EPOGEN® was launched in 1989, and we market it for the indication to treat anemia caused by CKD in patients on dialysis to lessen the need for red blood cell transfusions. The majority of our sales are to a large dialysis provider.

Other Marketed Products

We also market a number of other products, including KYPROLIS® (carfilzomib), Vectibix® (panitumumab), Nplate® (romiplostim), NEUPOGEN® (filgrastim), Repatha® (evolocumab), BLINCYTO® (blinatumomab), IMLYGIC® (talimogene laherparepvec), Corlanor® (ivabradine) and Parsabiv™ (etelcalcetide).

Patents

The following table describes our outstanding material patents for the indicated product by territory, general subject matter and latest expiry date. Certain of the European patents are the subject of supplemental protection certificates that provide additional protection for the product in certain European countries beyond the dates listed in the table (see footnotes).

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

Product	Territory	General subject matter	Expiration
Enbrel® (etanercept)	U.S.	Methods of treating psoriasis	8/13/2019
	U.S.	Aqueous formulation and methods of treatment using the formulation	6/8/2023
	U.S.	Fusion protein, and pharmaceutical compositions	11/22/2028
	U.S.	DNA encoding fusion protein, and methods of making fusion protein	4/24/2029
Aranesp® (darbepoetin alfa)	U.S.	Glycosylation analogs of erythropoietin proteins	5/15/2024
Prolia®/ XGEVA® (denosumab)	U.S.	RANKL antibodies; and methods of use(1)	12/22/2017
	U.S.	Methods of treatment	6/25/2022
	U.S.	Nucleic acids encoding RANKL antibodies, and methods of producing RANKL antibodies	11/30/2023
	U.S.	RANKL antibodies including sequences	2/19/2025
	Europe	Medical use of RANKL antibodies	4/15/2018
	Europe	RANKL antibodies including epitope binding	2/23/2021
	Europe	RANKL antibodies including sequences(2)	6/25/2022
Sensipar®/ Mimpara® (cinacalcet)	U.S.	Calcium receptor-active molecules	3/8/2018
	U.S.	Formulation	9/22/2026
	Europe	Calcium receptor-active molecules(2)	10/23/2015
KYPROLIS® (carfilzomib)	U.S.	Compositions and compounds	12/7/2027
	U.S.	Methods of treatment	4/14/2025
	Europe	Compositions, compounds and methods of treatment(2)	8/8/2025
Vectibix® (panitumumab)	U.S.	Human monoclonal antibodies to epidermal growth factor receptor (EGFr)	4/8/2020
	Europe	Human monoclonal antibodies to EGFr(2)	5/5/2018
Nplate® (romiplostim)	U.S.	Thrombopoietic compounds	1/19/2022
	U.S.	Formulation	2/12/2028
	Europe	Thrombopoietic compounds(2)	10/22/2019
	Europe	Formulation	4/20/2027
Repatha® (evolocumab)	U.S.	Antibodies(3)	10/25/2029
	U.S.	Methods of treatment	10/8/2030
	Europe	Compositions and method of treatment	8/22/2028
BLINCYTO® (blinatumomab)	U.S.	Bifunctional polypeptides(3)	4/21/2019
	U.S.	Method of administration	9/28/2027
	Europe	Bifunctional polypeptides(2)	11/26/2024
	Europe	Method of administration	11/29/2026
IMLYGIC® (talimogene laherparepvec)	U.S.	Compositions and method of treatment(3)	1/22/2021
	Europe	Composition and uses(2)	1/22/2021
Parsabiv™ (etelcalcetide)	U.S.	Compound and pharmaceutical composition	7/29/2030
	Europe	Compound and pharmaceutical composition	7/29/2030

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(1) The U.S. Patent and Trademark Office has issued a Notice of Final Determination that a patent with this subject matter is eligible for patent term extension with an expiry of September 17, 2021.

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

•denosumab — France, Italy, Spain and the United Kingdom, expiring in 2025
•cinacalcet — France, Germany, Spain and the United Kingdom, expiring in 2019; and Italy, expiring in 2020
•carfilzomib — France, Germany, Italy and Spain, expiring in 2030
•panitumumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2022
•romiplostim — France, Germany, Italy, Spain and the United Kingdom, expiring in 2024
•blinatumomab — France, Italy and Spain, expiring in 2029
•talimogene laherparepvec — Italy, expiring in 2026

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

Competition

We operate in a highly competitive environment. A number of our marketed products are indicated in disease areas where other products or treatments are currently available or are being pursued by our competitors through research and development (R&D) activities. We continue to pursue ways to increase the value of our medicines through innovations during their lifecycles. This can include expanding the disease areas for which our products are indicated and finding new methods to make the delivery of our medicines easier and less costly. Such activities can offer important opportunities for differentiation. For example, in 2015, we launched the Neulasta® Onpro® kit, which provides patients the opportunity to administer the recommended dose of Neulasta® at home the day after chemotherapy, thereby saving a trip back to the doctor. We also developed the AutoTouch™ reusable auto-injector to be used with Enbrel Mini™ single-dose prefilled cartridges (50 mg/mL), which was approved by the FDA in September 2017. The Enbrel Mini™ utilizes a new drug formulation of ENBREL that was associated with substantially significant lower mean injection site pain than the current formulation. We plan to continue pursuing such innovation efforts to strengthen our competitive position. Such position may be based on, among other things, safety, efficacy, reliability, availability, patient convenience/delivery devices, price, reimbursement, access to and timing of market entry and patent position and expiration.

Certain of the existing patents on our principal products have expired, and we face new and increasing competition, including from biosimilars and generics. We may also compete against biosimilar or generic versions of our competitors' products. A biosimilar is another version of a biological product for which marketing approval is sought or has been obtained based on a demonstration that it is "highly similar" to the original reference product. See Government Regulation. We expect that the adverse impact from biosimilars will be more like branded biologic competition than that seen when branded small molecules face generics. Although we expect biosimilars to compete on price, we believe many patients, providers and payers will continue to place high value on the reputation, reliability and safety of our products. Zarxio®, a biosimilar version of NEUPOGEN® from Sandoz, a Novartis company (Sandoz), which launched in the United States in 2015, was the first biosimilar entrant into the U.S. market. Companies have pending applications with the FDA for biosimilar versions of EPOGEN® and Neulasta®, along with additional biosimilar versions of NEUPOGEN®. See also Government Regulation—Regulation in the United States—Approval of Biosimilars. As biosimilar competitors come to market, we will leverage both the experience we have had in the United States versus branded competition, and our experience in competing against epoetin alfa and filgrastim biosimilars in Europe.

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

Factors—Our products face substantial competition and Item 1A. Risk Factors—We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future.

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

Product	Territory	Competitor marketed product	Competitors
ENBREL	U.S. & Canada	REMICADE®*	Janssen Biotech, Inc. (Janssen)[1]
	U.S. & Canada	HUMIRA®	AbbVie Inc.
	U.S. & Canada	STELARA®[2]	Janssen[1]
	U.S. & Canada	Otezla®[2]	Celgene Corporation (Celgene)
Neulasta®[3]	Europe	Filgrastim biosimilars	Various
Aranesp®	U.S.	PROCRIT®[4]	Janssen[1]
	U.S.	MIRCERA®[5]	Galenica Group (Galenica)/F. Hoffmann-La Roche Ltd. (Roche)
	Europe	Epoetin alfa biosimilars	Various
Prolia®	U.S. & Europe	Alendronate, raloxifene and zoledronate generics	Various
Sensipar®[6]/ Mimpara®	U.S. & Europe	Active vitamin D analogs	Various
XGEVA®	U.S. & Europe	Zoledronate generics	Various
EPOGEN®[3]	U.S.	MIRCERA®[5]	Galenica/Roche
KYPROLIS®[8]	U.S.	VELCADE®	Millennium Pharmaceuticals, Inc.[7]
	U.S.	REVLIMID®	Celgene
	U.S.	POMALYST®	Celgene
	U.S.	DARZALEX®	Janssen[1]
Repatha®	U.S. & Europe	PRALUENT®	Regeneron Sanofi

* Approved biosimilars available.

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

(2) Dermatology only.

(3) Biosimilars under regulatory review in the United States.

(4) PROCRIT® competes with Aranesp® in the supportive cancer care and pre-dialysis settings.

(5) MIRCERA® competes with Aranesp® only in the nephrology segment.

(6) Our U.S. composition of matter patent for Sensipar® expires in March 2018. We are engaged in litigation with a number of companies seeking to market generic versions of Sensipar® surrounding our U.S. formulation patent that expires in September 2026. See Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements, for further information. Several of these generic versions of Sensipar® have been tentatively approved by the FDA.

(7) A subsidiary of Takeda Pharmaceutical Company Limited.

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

Reimbursement

Sales of our principal products are dependent on the availability and extent of coverage and reimbursement from third-party payers. In many markets around the world, these payers, including government health systems, private health insurers and other organizations, remain intensely focused on reducing the cost of healthcare. Their efforts have intensified as a result of rising healthcare costs and economic challenges. Drugs, and in particular specialty drugs such as our products, remain heavily scrutinized for cost containment. As a result, payers are being more restrictive regarding the use of biopharmaceutical products, while requiring a higher level of clinical evidence to support the

benefit such products bring to patients and the broader healthcare system.

In the United States, biopharmaceutical product pricing remains central to discussions on controlling healthcare costs. The pricing practices of certain companies have increased public media and government scrutiny of the biopharmaceutical industry,

providing greater incentive for governments and private payers to limit or regulate the prices of drug products and services. Policymakers from both major U.S. political parties, including key members of the presidential administration, have indicated their support for pursuing policies to lower drug costs for patients. At the same time, value assessments of new technologies, previously used predominantly outside the United States, are having an impact in the U.S. healthcare environment. Healthcare provider organizations and independent organizations are creating their own value assessments of biopharmaceutical drugs for comparison with manufacturer pricing. Although these organizations do not set drug prices, they seek to influence pricing as well as payer and provider decision making by publicly disclosing their assessments, often making assertions around what they believe to be the appropriate price to charge for a product. In addition, continued consolidation of payers and integration of providers and payers (integrated delivery systems) increase the level of market power held by our customers. These developments put greater pressure on access to, pricing of and sales of our products.

In the United States, healthcare providers are reimbursed for covered services and products they deliver through Medicare, Medicaid and other government healthcare programs, as well as through private payers. Pharmacies are also reimbursed in a similar manner for drug products they dispense. We are required to provide rebates or discounts on our products that are reimbursed through certain government programs, including Medicare and Medicaid, and also provide discounts to qualifying health care providers under the Federal 340B Drug Pricing Program. These rebates and/or discounts levels, as well as entities who are entitled to receive them, have increased over time. For example, the Patient Protection and Affordable Care Act (ACA), enacted in 2010, increased many of the mandatory discounts and rebates required of us. The ACA also imposed a new Branded Prescription Pharmaceutical Manufacturers and Importers fee payable each year by us and other manufacturers. The U.S. presidential administration has identified repealing and replacing the ACA as a priority. In the tax reform bill signed by President Trump in December 2017, Congress removed a key ACA provision by repealing the individual mandate penalty which required each individual to have health insurance or pay a penalty. Future changes to government programs such as the ACA, whether legislative or regulatory, could impact the number of patient lives covered, could raise or lower the cost of quality insurance, could affect Medicaid eligibility and could change levels of patient protections provided unless alternatives are put in place.

Additional efforts by state legislatures and government agencies in the United States could also affect us and our industry. For example, a recently enacted California law requires manufacturers to provide payers advance notice of a price increase over a specified threshold, and a Vermont law requires manufacturers to submit price increase justifications to the state attorney general if certain price increase and state-spending thresholds are met. Examples of other proposals that have been discussed and debated, but not yet enacted, include state ballot initiatives that would place a maximum price ceiling, or cap, on pharmaceutical products purchased by state agencies and state legislative efforts to cap pharmaceutical prices for commercial payers. Other government legislative and regulatory actions that would have a significant impact on Amgen include: changes to how the Medicare program covers and reimburses current and future drugs, including for patients with End-Stage Renal Disease; changes in the Federal payment rate or new rebate requirements for covered drugs and policies for drug payment in Medicare or Medicaid; and changes to coverage and payment for biosimilars, such as policies that would enable easier substitution for, or provide reimbursement advantages over, the corresponding innovative products. Centers for Medicare & Medicaid Services (CMS) has indicated interest in testing new models for drug payment in Medicare Part B and Part D. CMS also continues to test alternative payment models with providers, such as the Oncology Care Model. These models provide financial incentives to providers who participate under which providers take on greater risk for the overall cost and quality of care. In addition, CMS recently finalized changes to Medicare payment to hospitals for Part B drugs acquired through the Federal 340B Drug Pricing Program but provide financial incentive for hospitals to use biosimilar products over the corresponding innovative products. CMS is also proposing changes to Medicare Part D and Medicare Advantage. These and/or other changes have the potential to impact prescribing and patient access to Amgen’s therapies.

In the U.S. private sector, payers continue to institute cost reduction and containment measures that lower drug utilization and/or spending altogether and/or shift a greater portion of the costs to patients. Such measures include more limited benefit plan designs, higher patient co-pays or coinsurance obligations, limitations on patients’ use of

commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs), higher-tier formulary placement that increases the level of patient out-of-pocket costs and/or stricter utilization management criteria before a patient may get access to a drug. In the specialty pharmacy sector, in which the majority of our sales for ENBREL and Repatha® occur, the use of such measures by Pharmacy Benefit Managers (PBMs) and insurers has continued to intensify which have limited Amgen product usage and sales. PBMs are third-party organizations tasked with administrating prescription drug programs for large employers, health plans and government programs. Consolidation has resulted in a smaller number of PBMs and insurers overseeing a large portion of total covered lives in the United States. As a result, PBMs and insurers have greater market power and negotiating leverage to exclude drugs from their formularies in favor of competitor drugs or alternative treatments, and/or to mandate stricter utilization criteria. Formulary exclusion effectively encourages patients and providers to seek alternative treatments or pay 100% of the cost of a drug. Our experience with Repatha® underscores that utilization management requirements, including the burdensome administrative processes required of physicians to demonstrate and document that patients meet such requirements, continue to be a significant challenge for patients and physicians, limiting access for appropriate usage. Even when access is available, some patients abandon their prescriptions due to economic reasons. In highly competitive treatment markets such as

with ENBREL and Repatha®, PBMs are also able to exert negotiating leverage by requiring incremental rebates from manufacturers in order to maintain their formulary position. A drug's inclusion and favorable positioning on formulary is essential to ensure patients have access.

In many countries outside the United States, government-sponsored healthcare systems are the primary payers for drugs and biologics. With increasing budgetary constraints, payers in many countries are applying a variety of measures to exert downward price pressure. These measures can include mandatory price controls, price referencing, therapeutic reference pricing, increases in mandates or incentives for generic substitution and biosimilar usage, and government-mandated price cuts. In this regard, many countries have Health Technology Assessment (HTA) organizations that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies, and these organizations are expanding in established and emerging markets. We expect that countries will continue to take aggressive actions to seek to reduce expenditures on drugs and biologics. Similarly, fiscal constraints may also impact the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

The dynamics and developments discussed above serve to create pressure on the pricing and potential usage of our products, and the industry as a whole. We remain focused on delivering breakthrough treatments for unmet medical needs. Amgen is committed to working with the entire healthcare community to ensure continued innovation and to enable patient access to needed medicines. We do this by:

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

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

Manufacturing, Distribution and Raw Materials

Manufacturing

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

Our internal manufacturing network has the commercial production capabilities of bulk manufacturing, formulation, fill, finish and device assembly. These activities are performed within the United States and its territories in our Puerto Rico, Rhode Island and California facilities, as well as internationally in our Ireland, Netherlands and Singapore facilities. In addition, we utilize third-party contract manufacturers to supplement our commercial manufacturing requirements. We utilize these internal facilities and third-party contract manufacturers to develop similar capabilities in multiple geographic areas to mitigate potential supply impacts of the most important risks facing our supply chain. In September 2017, Hurricane Maria made landfall on the island of Puerto Rico causing some damage to our facility in Juncos. Critical manufacturing areas of our facility were not significantly affected, and we have resumed our full manufacturing operations. Further recovery efforts on the island are ongoing. We have continued to provide an uninterrupted supply of medicines for patients around the world.

We manufacture products to support our clinical trials primarily at our California and Rhode Island facilities. We also utilize third-party contract manufacturers for certain clinical products.

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

Distribution

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

Other

In addition to the manufacturing and distribution activities noted above, our operations in the United States, the U.S. territory of Puerto Rico and the Netherlands include key manufacturing support functions, including quality control, process development, procurement, production scheduling and warehousing. Certain of those manufacturing and distribution activities are highly regulated by the FDA as well as other international regulatory agencies. See Government Regulation—Regulation in the United States—Regulation of Manufacturing Standards.

Manufacturing Initiatives

We have multiple ongoing initiatives that are designed to extend our manufacturing advantage by optimizing our manufacturing network and/or mitigating risks while continuing to ensure adequate supply of our products. In 2017, our new biologics manufacturing facility in Singapore was licensed by the FDA and EMA for certain commercial scale production. The Singapore facility was completed in approximately half the time typically required for conventional biomanufacturing equivalents. It utilizes a flexible and modular design that can be replicated in future facilities, enabling higher production and accessibility to patients around the world. The Singapore facility is fully reconfigurable, allowing the production of other products for worldwide supply. For example, in October 2017, we completed a second bulk process qualification campaign, which, if approved, would enable a second molecule to be manufactured at that facility. We also completed the construction of a second facility in Singapore and we are currently carrying out a qualification campaign.

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

Raw Materials and Medical Devices

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

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

Government Regulation

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

Regulation in the United States

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

Clinical Development and Product Approval. Drug development in our industry is complex, challenging and risky; and failure rates are high. Product development cycles are typically very long—approximately 10 to 15 years from discovery to market. A potential new medicine must undergo many years of preclinical and clinical testing to establish its safety and efficacy for use in humans at appropriate dosing levels and with an acceptable risk-benefit profile. After laboratory analysis and preclinical testing in animals, we file an Investigational New Drug Application (IND) with the FDA to begin human testing. Typically, we undertake an FDA-designated three-phase human clinical testing program.

- In phase 1, we conduct small clinical trials to investigate the safety and proper dose ranges of our product candidates in a small number of human subjects.
- In phase 2, we conduct clinical trials to investigate side-effect profiles and the efficacy of our product candidates in a large number of patients who have the disease or condition under study.
- In phase 3, we conduct clinical trials to investigate the safety and efficacy of our product candidates in a large number of patients who have the disease or condition under study.

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

Approval of Biosimilars. The ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. The pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on the non-clinical and clinical trial data of an originator product to which the biosimilar has been demonstrated to be "highly similar" and to have no clinically meaningful differences in terms of safety, purity and potency. The relevance of demonstrating "similarity" is that in many cases, biosimilars can be brought to market without conducting the full suite of clinical trials typically required of originators, as risk-benefit has previously been established. In order to preserve incentives for future innovation, the law establishes a period of exclusivity for originators' products, which in general prohibits biosimilars from gaining FDA approval based in part on reliance on or reference to the originator's data in their application to the FDA for 12 years after FDA approval of the originator product. The law does not change the duration of patents granted on biologic products. The FDA has released a number of guidance documents as part of the implementation of the abbreviated approval pathway for biosimilars, some of which remain in draft form. As of the end of 2017, seven biosimilar applications have been approved by the FDA, including our products AMJEVITA™ and MVASI,™ as well as competitors to our products ENBREL and NEUPOGEN®. A number of manufacturers have announced the filing of marketing applications to the FDA under the biosimilar pathway, some of which are for biosimilars of our products.

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

Regulation of Manufacturing Standards. The FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of products prior to providing approval to market products. If after receiving approval from the FDA, we make a material change in manufacturing equipment, location or process,

additional regulatory review may be required. We also must adhere to current Good Manufacturing Practice regulations and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA conducts regular, periodic visits to re-inspect our equipment, facilities, laboratories and processes following an initial approval.

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

Regulation Outside the United States

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

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

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

As a result of the vote by the United Kingdom (UK) to leave the EU in March 2019, the EMA announced on November 20, 2017 that it will relocate its headquarters from London to Amsterdam by March 30, 2019. In addition to uncertainty regarding the supervision and regulation of our products in the UK, it is unclear what impact the EMA move will have on the EU marketing approval process.

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

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

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

Post-approval Phase

After approval, we continue to monitor adverse events and product complaints reported following the use of our products through routine post-marketing surveillance and studies when applicable. We report such events to the appropriate regulatory agencies, as required per local regulations for individual cases and aggregate reports. We proactively monitor (according to good pharmacovigilance practices) and ensure implementation of signal detection, assessment and the communication of adverse events that may be associated with the use of our products. We also

proactively monitor product complaints through our quality systems, which includes assessing our drug delivery devices for device complaints, adverse events and malfunctions. We may also be required by regulatory agencies to conduct further clinical trials on our marketed products as a condition of their approval or to provide additional information on safety and efficacy. Health authorities, including the FDA, have authority to mandate labeling changes to products at any point in a product's lifecycle based on new safety information or as part of an evolving label change to a particular class of products.

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

Other Regulation

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

In 2012, Amgen announced it had finalized a settlement agreement with the U.S. government and various other parties regarding allegations that Amgen's promotional, contracting, sales and marketing activities and arrangements caused the submission of various false claims under the Federal Civil False Claims Act and various State False Claims Acts. In connection with entering into the settlement agreement, Amgen also entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services that requires Amgen to maintain its corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years. Although the corporate integrity agreement term ended in December 2017, certain of the corporate integrity agreement's reporting obligations to OIG continue into 2018. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that in the future our practices might be further challenged under anti-kickback or similar laws.

Additionally, the U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA arguably includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

Our business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or regulations.

Research and Development and Selected Product Candidates

We focus our R&D on novel human therapeutics for the treatment of serious illness primarily in the areas of oncology/hematology, cardiovascular disease, inflammation, bone health, nephrology and neuroscience. We capitalize on our strength in human genetics, novel biology and protein engineering. We leverage our biologic expertise and take a modality-independent approach to R&D. We use cutting-edge science and technology to study subtle biological mechanisms in search of therapies that will improve the lives of those who suffer from diseases. Our discovery research programs may therefore yield targets that lead to the development of human therapeutics delivered as large molecules, small molecules, other combination modalities or new modalities. Leveraging two decades of research at deCODE, a global leader in analyzing the human genome, we are reshaping our portfolio and increasingly focusing efforts on targets validated in humans. Human genetic validation is used whenever possible in order to enhance the likelihood of success. For the years ended December 31, 2017, 2016 and 2015, our R&D expenses were $3.6 billion, $3.8 billion and $4.1 billion, respectively.

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

Our clinical trial activities are conducted by both our internal staff and third-party contract clinical trial service providers. To increase the number of patients available for enrollment in our clinical trials, we have opened clinical sites and will continue opening clinical sites and enrolling patients in a number of geographic locations. See Government Regulation—Regulation in the Unites States—Clinical Development and Product Approval for a discussion of government regulation over clinical development. Also see Item 1A. Risk Factors—We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.
Some of our competitors are actively engaged in R&D in areas in which we have products or in which we are developing product candidates or new indications for existing products. For example, we compete with other clinical trials for eligible patients, which may limit the number of available patients who meet the criteria for certain clinical trials. The competitive marketplace for our product candidates is significantly dependent on the timing of entry into the market. Early entry may have important advantages

in gaining product acceptance, thereby contributing to a product's eventual success and profitability. Accordingly, we expect that in some cases, the relative speed with which we can develop products, complete clinical testing, receive regulatory approval and supply commercial quantities of a product to the market will be important to our competitive position.

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

The following table shows a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 12, 2018, unless otherwise indicated. Additional product candidate information can be found on our website at www.amgen.com. (The website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.) The information in this section does not include other, non-registrational clinical trials that we may conduct for purposes other than for submission to regulatory agencies for their approval of a new product indication. We may conduct non-registrational clinical trials for various reasons including to evaluate real-world outcomes or to collect additional safety information with the use of our products. In addition, the table does not include the biosimilar products we are developing, which are discussed later in this section.

Molecule	Disease/condition
Phase 3 Programs	
Aimovig™	Migraine prevention
Aranesp®	Myelodysplastic syndromes
BLINCYTO®	ALL
ENBREL	Psoriatic arthritis; Rheumatoid arthritis remission
EVENITY™	Postmenopausal osteoporosis; Male osteoporosis
IMLYGIC®	Metastatic melanoma
KYPROLIS®	Multiple myeloma
Omecamtiv mecarbil	Chronic heart failure
Prolia®	Glucocorticoid-induced osteoporosis
Tezepelumab	Asthma
AMG 520 / CNP520	Alzheimer's disease
Phase 2 Programs	
BLINCYTO®	Diffuse Large B-Cell Lymphoma (DLBCL)
Tezepelumab	Atopic dermatitis
AMG 301	Migraine prevention
AMG 557	Primary Sjögren's syndrome
AMG 714	Celiac disease
Phase 1 Programs	
IMLYGIC®	Various cancer types
KYPROLIS®	Small-cell lung cancer
Oprozomib	Multiple myeloma
AMG 176	Various cancer types
AMG 224	Multiple myeloma
AMG 330	Acute myeloid leukemia
AMG 420	Multiple myeloma
AMG 570	Systemic lupus erythematosus
AMG 592	Inflammatory diseases
AMG 596	Glioblastoma
AMG 598	Obesity
AMG 673	Acute myeloid leukemia
AMG 701	Multiple myeloma
AMG 757	Small-cell lung cancer
AMG 820	Various cancer types
AMG 966	Inflammatory bowel diseases (Crohn's and ulcerative colitis)
AMG 986	Heart failure

Phase 3	Clinical trials investigate the safety and efficacy of product candidates in a large number of patients who have the disease or condition under study; typically performed with registrational intent.
Phase 2	Clinical trials investigate side effect profiles and efficacy of product candidates in a large number of patients who have the disease or condition under study.
Phase 1	Clinical trials investigate the safety and proper dose ranges of product candidates in a small number of human subjects.

Phase 3 Product Candidate Program Changes

As of February 13, 2017, we had 15 phase 3 programs. As of February 12, 2018, we had 13 phase 3 programs, as three programs were approved, two programs advanced into phase 3 and one program concluded. These changes are set forth in the following table.

Molecule	Disease/condition	Program change
Repatha®	Hyperlipidemia	sBLA approved by FDA
XGEVA®	Cancer-related bone damage in patients with multiple myeloma	sBLA approved by FDA
Vectibix®	Metastatic colorectal cancer for patients with wild-type RAS	sBLA approved by FDA
AMG 520 / CNP520	Alzheimer's disease	Advanced to phase 3
Tezepelumab	Severe uncontrolled asthma	Advanced to phase 3
XGEVA®	Delay or prevention of bone metastases in breast cancer	Concluded—study did not meet its primary endpoint

Phase 3 Product Candidate Patent Information

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

Molecule	Territory	General subject matter	Estimated expiration*
Aimovig™ (erenumab)	U.S.	Polypeptides	2031
	Europe	Polypeptides	2029
EVENITY™ (romosozumab)	U.S.	Polypeptides	2026
	Europe	Polypeptides	2026
Omecamtiv mecarbil	U.S.	Compound	2027
Tezepelumab	U.S.	Polypeptides	2029
	Europe	Polypeptides	2028
AMG 520 / CNP520	U.S.	Compound	2032
	Europe	Compound	2032

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

Phase 3 and 2 Program Descriptions

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

Aimovig™

Aimovig™ is a human monoclonal antibody that inhibits the receptor for calcitonin gene-related peptide. It is being evaluated for the prevention of migraine. Aimovig™ is being developed jointly with Novartis.

In July 2017, we announced that the FDA accepted for review the BLA for Aimovig™ for the prevention of migraine in patients experiencing four or more migraine days per month. The FDA has set a PDUFA target action date of May 17, 2018.

In January 2018, a phase 3b study met its primary endpoint and all secondary endpoints in patients with episodic migraine who had experienced two to four previous preventive treatment failures due to lack of efficacy or intolerable side effects.

Aranesp®

Aranesp® is a recombinant human protein agonist of the erythropoietin receptor. It is being investigated as a treatment for low risk myelodysplastic syndromes.

In October 2017, we announced that a phase 3 post-marketing requirement study to evaluate the safety and efficacy of Aranesp® in anemic patients with advanced non-small cell lung cancer receiving multi-cycle chemotherapy successfully met its primary endpoint of non-inferiority in overall survival compared to placebo, with no new safety findings.

BLINCYTO®

BLINCYTO® is an anti-CD19 x anti-CD3 (BiTE®) bispecific antibody construct.

A phase 2/3 study in patients with relapsed or refractory DLBCL is ongoing. In December 2017, we announced that the FDA accepted for priority review the sBLA for the treatment of minimal residual disease in patients with ALL. The PDUFA target action date is March 29, 2018.

In July 2017, we announced that the FDA approved the sBLA for BLINCYTO® to include overall survival data from the phase 3 TOWER study. The approval converts BLINCYTO®'s accelerated approval to a full approval. The approval expands the indication of BLINCYTO® for the treatment of relapsed or refractory B-cell precursor ALL in adults and children.

In February 2018, we announced that the CHMP of the EMA adopted a positive opinion recommending a label variation for BLINCYTO® to include overall survival data from the phase 3 TOWER study supporting the conversion of the conditional marketing authorization to a full marketing authorization in adult patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL.

ENBREL

ENBREL is a fusion protein that inhibits tumor necrosis factor.

Phase 3 studies to evaluate ENBREL as a monotherapy for psoriatic arthritis treatment and as a monotherapy in maintaining remission in rheumatoid arthritis are ongoing.

EVENITY™

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

In May 2017, we and UCB announced that the phase 3 ARCH study in postmenopausal women with osteoporosis met both primary endpoints and the key secondary endpoint. An imbalance in positively adjudicated cardiovascular serious adverse events was observed in the study as a new safety signal.

In July 2017, we and UCB announced that the FDA issued a Complete Response Letter for the BLA for EVENITY™ as a treatment for postmenopausal women with osteoporosis. The resubmission will include data from the phase 3 ARCH study and select data from the phase 3 BRIDGE study evaluating EVENITY™ in men with osteoporosis, in addition to the phase 3 FRAME study. We are currently evaluating all EVENITY™ data and will be working in close collaboration with the FDA.

In January 2018, we and UCB announced that the EMA accepted the MAA for EVENITY™ for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture.

IMLYGIC®

IMLYGIC® is an oncolytic immunotherapy derived from herpes simplex virus type 1.

A phase 1b/3 study to evaluate IMLYGIC® in combination with Merck & Company, Inc.'s (Merck's) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with mid- to late-stage metastatic melanoma is ongoing.

KYPROLIS®

KYPROLIS® is a proteasome inhibitor.

In July 2017, we announced positive results from the final analysis of the phase 3 ASPIRE study. The study met the key secondary endpoint of overall survival, demonstrating that KYPROLIS®, lenalidomide and dexamethasone reduced the risk of death by 21% over lenalidomide and dexamethasone alone. In December 2017, we submitted a sNDA to the FDA and a variation to the marketing authorization to the EMA to include the overall survival data from the ASPIRE study in the product label.

In October 2017, we announced top-line results of the phase 3 ARROW study, which showed KYPROLIS® administered once-weekly at the 70 mg/m^2 dose with dexamethasone allowed relapsed and refractory multiple myeloma patients to live 3.6 months longer without their disease worsening than KYPROLIS® administered twice-weekly at the 27 mg/m^2 dose with dexamethasone. The overall safety profile of the once-weekly KYPROLIS®

regimen was comparable to that of the twice-weekly regimen.

In January 2018, we announced that the CHMP of the EMA has adopted a positive opinion recommending a label variation for KYPROLIS® to include updated overall survival data from the phase 3 head-to-head ENDEAVOR study in patients with relapsed or refractory multiple myeloma. The ENDEAVOR study demonstrated that KYPROLIS® and dexamethasone reduced the risk of death by 21 percent, and increased overall survival by 7.6 months versus VELCADE® and dexamethasone.

A phase 3 study comparing carfilzomib, dexamethasone, and daratumumab to carfilzomib and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma is ongoing.

Omecamtiv mecarbil

Omecamtiv mecarbil is a small-molecule activator of cardiac myosin. It is being evaluated for the treatment of chronic heart failure. Omecamtiv mecarbil is being developed by Amgen in collaboration with Cytokinetics, Inc. and in collaboration with Servier for certain territories.

A phase 3 cardiovascular outcomes study for the treatment of chronic heart failure is ongoing.

Prolia®

Prolia® is a human monoclonal antibody that inhibits RANKL. It is being investigated for the treatment of glucocorticoid-induced osteoporosis.

In October 2017, we announced that the FDA accepted for review the sBLA for the treatment of patients with glucocorticoid-induced osteoporosis. The FDA has set a PDUFA target action date of May 28, 2018.

Tezepelumab (formerly AMG 157)

Tezepelumab is a human monoclonal antibody that inhibits the action of thymic stromal lymphopoietin. It is being evaluated as a treatment for asthma in an ongoing phase 3 study, as well as atopic dermatitis. Tezepelumab is being jointly developed in collaboration with AstraZeneca plc (AstraZeneca).

AMG 301

AMG 301 is a human monoclonal antibody that inhibits the pituitary adenylate cyclase-activating polypeptide type 1 (PAC1) receptor. It is being investigated for migraine prevention. AMG 301 is being jointly developed in collaboration with Novartis.

AMG 520 / CNP520

AMG 520 / CNP520 is a small molecule inhibitor of beta-site amyloid precursor protein-cleaving enzyme-1 (BACE). It is being evaluated for the prevention of Alzheimer’s disease, with phase 3 studies ongoing. AMG 520 / CNP520 is being jointly developed in collaboration with Novartis.

AMG 557

AMG 557 is a human monoclonal antibody that inhibits the action of the ICOS ligand. It is being investigated as a treatment for primary Sjögren’s syndrome. AMG 557 is being jointly developed in collaboration with AstraZeneca.

AMG 714

AMG 714 is a human monoclonal antibody that binds to Interleukin-15. It is being investigated for the treatment of celiac disease. In November 2017, Amgen reacquired the AMG 714 program from Celimmune LLC.

Amgen Development of Biosimilars

We continue to develop and commercialize biosimilar medicines. Our biosimilar product candidates are in varying stages of commercialization and clinical development as described in the following table:

Program	Reference product	Status
AMJEVITA™/ AMGEVITA™	adalimumab (HUMIRA®)	Approved by FDA and EC across all eligible indications of reference product
MVASI™*	bevacizumab (Avastin®)	Approved by FDA and EC across all eligible indications of reference product
ABP 710	infliximab (REMICADE®)	Phase 3 rheumatoid arthritis study ongoing
ABP 798*	rituximab (Rituxan® / Mabthera®)	Phase 3 rheumatoid arthritis study ongoing Phase 3 non-Hodgkin’s lymphoma study ongoing
ABP 959	eculizumab (Soliris®)	Phase 1 completed
ABP 980*	trastuzumab (Herceptin®)	BLA submitted to FDA; MAA submitted to EMA

* Developed in collaboration with Allergan

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Business Relationships

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

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

Kirin-Amgen, Inc.

On October 30, 2017, we announced that we agreed to acquire the remaining 50% ownership interest of Kirin-Amgen, Inc. (K-A) from Kirin Holdings Company, Limited (Kirin). We completed the share acquisition during the first quarter of 2018, making K-A a wholly owned subsidiary of Amgen. Prior to the closing of the share acquisition, K-A was a 50-50 joint venture with Kirin. K-A develops and then licenses all product rights which have been transferred from Amgen and Kirin. See Part IV—Note 21, Subsequent event, to the Consolidated Financial Statements.

K-A has given us exclusive licenses to manufacture and market: (i) granulocyte colony-stimulating factor (G-CSF) and pegfilgrastim in the United States, Europe, Canada, Australia, New Zealand, all Central American, South American, Middle Eastern and African countries and certain countries in Asia; (ii) darbepoetin alfa and romiplostim in the United States, Europe, Canada, Australia, New Zealand, Mexico, all Central and South American countries and certain countries in Central Asia, Africa and the Middle East; and (iii) recombinant human erythropoietin in the United States. We currently market pegfilgrastim, G-CSF, darbepoetin alfa, recombinant human erythropoietin and romiplostim under the brand names Neulasta®, NEUPOGEN®/GRANULOKINE®, Aranesp®, EPOGEN® and Nplate®, respectively. Under these agreements, Amgen pays K-A royalties based on product sales. In addition, Amgen also receives payments from K-A for milestones earned and for conducting certain R&D activities on its behalf.

K-A has also given Kirin exclusive licenses to manufacture and market: (i) G-CSF and pegfilgrastim in Japan, Taiwan and South Korea; (ii) darbepoetin alfa, romiplostim and brodalumab in Japan, China, Taiwan, South Korea and in certain other countries and/or regions in Asia; and (iii) recombinant human erythropoietin in Japan. K-A also gave Kirin and Amgen co-exclusive licenses to manufacture and market G-CSF, pegfilgrastim and recombinant human erythropoietin in China, which Amgen subsequently assigned to Kirin, and as a result, Kirin now exclusively manufactures and markets G-CSF and recombinant human erythropoietin in China. Kirin markets G-CSF, pegfilgrastim, darbepoetin alfa, romiplostim, recombinant human erythropoietin and brodalumab under the brand names GRAN®/Grasin®, Peglasta®/Neulasta®/G-Lasta®, NESP®/Aranesp®, ROMIPLATE®, ESPO® and LUMICEF®, respectively. Under these agreements, Kirin pays K-A royalties based on product sales. In addition, Kirin also receives payments from K-A for conducting certain R&D activities on its behalf.

K-A has also given J&J exclusive licenses to manufacture and market recombinant human erythropoietin for all geographic areas of the world outside the United States, China and Japan. Under this agreement, J&J pays royalties to K-A based on product sales. See Part IV—Note 8, Related party transactions, to the Consolidated Financial Statements.

Novartis

In April 2017, we expanded our existing migraine collaboration with Novartis. In the United States, Amgen and Novartis will jointly develop and collaborate on the commercialization of Aimovig™. Amgen, as the principal, will recognize product sales of Aimovig™ in the United States, will share U.S. commercialization costs with Novartis and will pay Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig™ and other specified migraine programs. Novartis will pay Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories. Novartis will fund a portion of global R&D expenses. Novartis will also make payments to Amgen that

could collectively amount to approximately $400 million if certain regulatory events occur and commercial thresholds are achieved with respect to Aimovig™ in the United States. Amgen will manufacture and supply Aimovig™ worldwide.

Pfizer Inc.

The co-promotion term of our ENBREL collaboration agreement with Pfizer Inc. (Pfizer) in the United States and Canada expired on October 31, 2013. Under this agreement, we paid Pfizer a profit share until October 31, 2013, and residual royalties from November 1, 2013 to October 31, 2016, which were significantly less than the profit share payments. In 2015 and 2016, the residual royalty payments ranged from 11% to 10% of annual net ENBREL sales in the United States and Canada. Effective November 1, 2016, there are no further royalty payments.

UCB

We are in a collaboration with UCB for the development and commercialization of EVENITY.™ In 2016, we amended the commercialization rights and responsibilities of the parties. Under the amended agreement, we have the rights to commercialize EVENITY™ for all indications in the United States, Japan and Hong Kong. UCB has the rights for Europe, China and Brazil. The rest of the countries have been allocated to Amgen. Generally, development costs and future worldwide commercialization profits and losses related to the collaboration after accounting for expenses are shared equally.

Bayer HealthCare Pharmaceuticals Inc.

We are in a collaboration with Bayer HealthCare Pharmaceuticals Inc. (Bayer) to jointly develop and commercialize Nexavar® (sorafenib). In 2015, we amended the terms of our collaboration agreement with Bayer, which terminated the co-promotion agreement in the United States, and transferred all U.S. operational responsibilities to Bayer, including commercial and medical affairs activities. Prior to the termination of the co-promotion agreement, we co-promoted Nexavar® with Bayer and shared equally in the profits in the United States. In lieu of this profit share, Bayer now pays us a royalty on U.S. sales of Nexavar® at a percentage rate in the high 30s. Outside of the United States, excluding Japan, Bayer manages all commercialization activities and incurs all of the sales and marketing expenditures and mutually agreed R&D expenses, and we reimburse Bayer for half of those expenditures. In all countries outside of the United States, except Japan, we receive 50% of net profits on sales of Nexavar® after deducting certain Bayer-related costs. The rights to develop and market Nexavar® in Japan are reserved to Bayer.

DaVita Inc.

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

Human Resources

As of December 31, 2017, Amgen had approximately 20,800 staff members. We consider our staff relations to be good.

Executive Officers of the Registrant

The executive officers of the Company as of February 7, 2018, are set forth below.

Mr. Robert A. Bradway, age 55, has served as a director of the Company since October 2011 and Chairman of the Board of Directors since 2013. Mr. Bradway has been the Company's President since 2010 and Chief Executive Officer since 2012. From 2010 to 2012, Mr. Bradway served as the Company's President and Chief Operating Officer. Mr. Bradway joined the Company in 2006 as Vice President, Operations Strategy and served as Executive Vice President and Chief Financial Officer from 2007 to 2010. Prior to joining the Company, he was a Managing Director at Morgan Stanley in London where, beginning in 2001, he had responsibility for the firm's banking department and corporate finance activities in Europe. Mr. Bradway has been a director of The Boeing Company, an aerospace company and manufacturer of commercial airplanes, defense, space and securities systems, since 2016. He has served on the board of trustees of the University of Southern California since 2014, and on the advisory board of the Leonard D. Schaeffer Center for Health Policy and Economics at that university since 2012. From 2011 to May 2017, Mr. Bradway was a director of Norfolk Southern Corporation, a transportation company.

Mr. Jonathan P. Graham, age 57, became Senior Vice President, General Counsel and Secretary in 2015. From 2006 to 2015, Mr. Graham was Senior Vice President and General Counsel at Danaher Corporation. From 2004 to 2006, Mr. Graham was Vice President, Litigation and Legal Policy at General Electric Company (GE). Prior to GE, Mr. Graham was a partner at Williams & Connolly LLP.

Dr. Sean E. Harper, age 55, became Executive Vice President, Research and Development in 2012. Dr. Harper joined the Company in 2002, and has held leadership roles in early development, medical sciences and global regulatory and safety. Dr. Harper served as Senior Vice President, Global Development and Corporate Chief Medical Officer from 2007 to 2012. Prior to joining the Company, Dr. Harper worked for five years at Merck Research Laboratories.

Mr. Anthony C. Hooper, age 63, became Executive Vice President, Global Commercial Operations in 2011. From 2010 to 2011, Mr. Hooper was Senior Vice President, Commercial Operations and President, U.S., Japan and Intercontinental of Bristol-Myers Squibb Company (BMS). From 2009 to 2010, Mr. Hooper was President, Americas of BMS. From 2004 to 2009, Mr. Hooper was President, U.S. Pharmaceuticals, Worldwide Pharmaceuticals Group, a division of BMS. Prior to this, Mr. Hooper held various senior leadership positions at BMS. Prior to joining BMS, Mr. Hooper was Assistant Vice President of Global Marketing for Wyeth Laboratories.

Ms. Lori A. Johnston, age 53, became Senior Vice President in 2016. From 2012 to 2016, Ms. Johnston was Executive Vice President and Chief Administrative Officer of Celanese Corporation. From 2006 to 2012, Ms. Johnston served in a series of progressive leadership roles at Amgen, with her last position being Vice President, Human Resources. Prior to joining the Company, Ms. Johnston held human resources and other positions at Dell Inc.

Mr. David W. Meline, age 60, became Executive Vice President and Chief Financial Officer in 2014. From 2011 to 2014, Mr. Meline served as Senior Vice President and Chief Financial Officer at 3M Company (3M). From 2008 to 2011, Mr. Meline served as Vice President, Corporate Controller and Chief Accounting Officer of 3M. Prior to 2008, Mr. Meline served in a variety of senior leadership roles for General Motors Company for over 20 years, with his last position being Vice President and Chief Financial Officer, North America. Mr. Meline has been a director of ABB Ltd., a global industrial technology company based in Switzerland, since 2016, serving as a member of the Finance, Audit and Compliance Committee. Mr. Meline was a director of TRW Automotive Holdings, Corp., a supplier of automotive systems, modules and components, from 2014 until its acquisition by ZF Friedrichshafen AG in 2015.

Ms. Cynthia M. Patton, age 56, became Senior Vice President and Chief Compliance Officer in 2012. Ms. Patton joined the Company in 2005. From 2005 to 2010, Ms. Patton was Associate General Counsel. From 2010 to 2012, Ms. Patton was Vice President, Law. Previously, Ms. Patton served as Senior Vice President, General Counsel and Secretary of SCAN Health Plan from 1999 to 2005.

Mr. David A. Piacquad, age 61, became Senior Vice President, Business Development in 2014. Mr. Piacquad joined the Company in 2010 and, until 2014, served as Vice President, Strategy and Corporate Development. From 2014 to 2014, Mr. Piacquad served as Vice President, Business Development. Prior to joining the Company, from 2009 to 2010, Mr. Piacquad was Principal of David A. Piacquad Consulting LLC. From 2006 to 2009, Mr. Piacquad served as Senior Vice President, Business Development and Licensing for Schering-Plough Corporation. Prior to Schering-Plough, Mr. Piacquad served in a series of leadership roles in finance and business development at J&J, with

his last position being Vice President, Ventures and Business Development.

Mr. Esteban Santos, age 50, became Executive Vice President, Operations in 2016. Mr. Santos joined the Company in 2007 as Executive Director, Manufacturing Technologies. From 2008 to 2013, Mr. Santos held a number of Vice President roles at the Company in engineering, manufacturing, site operations and drug product. From 2013 to 2016, Mr. Santos was Senior Vice President, Manufacturing. Prior to joining the Company, Mr. Santos served as Site General Manager for J&J's Cordis operation in Puerto Rico. Prior to J&J, Mr. Santos held several management positions in GE's industrial and transportation businesses.

Geographic Area Financial Information

For financial information concerning the geographic areas in which we operate, see Part IV—Note 19, Segment information—Geographic information, to the Consolidated Financial Statements.

Investor Information

Financial and other information about us is available on our website at www.amgen.com. We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission (SEC). In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected, without charge, at the SEC's public reference room at 100 F Street NE, Washington, DC 20549, or at the SEC's website at www.sec.gov. (These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.) Information related to the operation of the SEC's public reference room may be obtained by calling the SEC at 800-SEC-0330.

Item 1A. RISK FACTORS

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

Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability.

Sales of our products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers continue to pursue aggressive initiatives to contain costs and manage drug utilization and are increasingly focused on the effectiveness, benefits and costs of similar treatments, which could result in lower reimbursement rates for our products or narrower populations for whom our products will be reimbursed by payers. Intense public scrutiny of the price of drugs and other healthcare costs continues and greater focus on pricing and price increases may limit our ability to set or increase the price of our products based on their value, which could have a material adverse effect on our product sales, business and results of operations.

A substantial portion of our U.S. business relies on reimbursement from U.S. federal government healthcare programs and commercial insurance plans regulated by the U.S. federal and state governments. See Item 1. Business—Reimbursement. Changes to U.S. federal reimbursement policy may come through legislative and/or administrative actions. Discussions continue around a number of potential legislative changes that could affect the reimbursement and/or pricing of our products, including proposals to allow the U.S. federal government to directly negotiate drug prices with pharmaceutical manufacturers and to require manufacturers to pay higher rebates in the Medicare Part D setting. Legislation has been introduced into the U.S. Congress for other proposals, including legislation designed to overhaul provisions of the ACA as well as to enable commercial-level re-importation of prescription medications from Canada or other countries. State government actions or ballot initiatives can also affect how our products are covered and reimbursed or create additional pressure on how our products are priced. Some states have adopted, and many other states have discussed and debated and are considering, new pricing legislation, including state proposals designed to require biopharmaceutical manufacturers to publicly report proprietary pricing information, limit price increases or to place a maximum price ceiling, or cap, on pharmaceutical products. For example, in October 2017, California's governor signed into law a new drug pricing transparency bill that requires pharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. Existing and proposed pricing legislation could lead to

the introduction and passage of additional bills or ballot initiatives in other states. While we are unable to predict if additional changes may ultimately be enacted, to the extent that these or other changes affect how our products are priced, paid for and reimbursed by government and private payers in the United States our business could be adversely impacted. Changes in U.S. federal reimbursement policy may also arise as a result of regulations or demonstration projects implemented by the CMS, the federal agency responsible for administering Medicare, Medicaid and the Health Insurance Marketplaces. CMS has substantial power to quickly implement policy changes that can significantly affect how our products are covered and reimbursed. Further, CMS is undertaking other projects to test care models, such as the CMS Oncology Care Model that provides participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare

costs without negatively impacting the efficacy of care. We believe the Oncology Care Model has impacted utilization of certain of our oncology products by participating physician practices and may continue to do so in the future. CMS has also solicited suggestions regarding other potential care models. In addition, the timing of reimbursement policy decisions can affect our business. Legislative or regulatory changes in the United States or other federal or state government initiatives that decrease the coverage or reimbursement available for our products, require that we pay increased rebates, limit our ability to offer co-pay payment assistance to commercial patients, limit the pricing of pharmaceutical products or reduce the use of our U.S. products could have a material adverse effect on our business and results of operations.

Payers, including healthcare insurers, PBMs and group purchasing organizations, increasingly seek ways to reduce their costs. Many payers continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients. Such measures include more limited benefit plan designs, higher patient co-pay or co-insurance obligations and limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs.) Payers also increasingly seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage. Payers also control costs by imposing restrictions on access to or usage of our products, such as by requiring prior authorizations or step therapy, and may choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. For example, some providers do not complete the burdensome administrative process required to demonstrate or document that the patients for whom Repatha® has been prescribed meet the payers' utilization management criteria and, as a result, patients do not gain access to Repatha® treatment. Further, other patients may obtain coverage for Repatha® but abandon their prescriptions rather than pay their co-pay payment. Significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. Further consolidation among insurers, PBMs and other payers, including through integrated delivery systems, would increase the negotiating leverage such entities have over us and other drug manufacturers. Ultimately, further discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products.

Outside the United States, we expect countries will continue to take aggressive actions to reduce their healthcare expenditures. See Item 1. Business—Reimbursement. For example, international reference pricing (IRP) is widely used by a large number of countries to control costs based on an external benchmark of a product's price in other countries. IRP policies can quickly and frequently change and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. Any deterioration in the coverage and reimbursement available for our products or in the timeliness or certainty of payment by payers to physicians and other providers could negatively impact the ability or willingness of healthcare providers to prescribe our products for their patients or could otherwise negatively affect the use of our products or the prices we receive for them. Such changes could have a material adverse effect on our product sales, business and results of operations.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products. In the United States, pricing data that we submit to the U.S. government impacts the payment rates for providers, rebates we pay, and discounts we are required to provide under Medicare, Medicaid and other government drug programs. Government price reporting regulations are complex and may require a manufacturer to update certain previously submitted data. Our price reporting data calculations are reviewed monthly and quarterly, and based on such reviews we have on occasion restated previously reported pricing data to reflect changes in calculation methodology, reasonable assumptions and/or underlying data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data, we also may be required to pay additional rebates and provide additional discounts.

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

We currently face competition from biosimilars in both Europe and the United States, and we expect to face increasing biosimilar and/or generics competition this year and beyond. Expiration or successful challenge of

applicable patent rights or expiration of an applicable data exclusivity period would accelerate such competition, and we expect to face more litigation regarding the validity and/or scope of our patents. Our products may also experience greater competition from lower-cost biosimilars or generics that come to market when branded products that compete with our products lose their own patent protection. To the extent that governments adopt more permissive approval frameworks and competitors are able to obtain broader or expedited marketing approval for biosimilars and generics, the rate of increased competition for our products could accelerate.

In the EU, biosimilars are evaluated and authorized pursuant to a set of general and product class-specific guidelines. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU countries have adopted and others are attempting to adopt biosimilar uptake measures such as requiring physician prescribing quotas or promoting switching or pharmacy substitution of biosimilars for the corresponding reference products, and other countries may adopt similar measures. Some EU countries impose automatic price reductions upon market entry of one or more biosimilar competitors.

In the United States, the ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. See Item 1. Business—Government Regulation—Regulation in the United States—Approval of Biosimilars. The first biosimilar entrant into the U.S. market, Sandoz's Zarxio®, is a biosimilar version of NEUPOGEN®, and was launched in the United States in 2015. Since then, the FDA has approved additional biosimilars, including a biosimilar version of ENBREL. In addition, a growing number of companies have announced that they are in varying stages of development of biosimilar versions of existing biotechnology products, including biosimilars that would compete with our products. Companies pursuing development of biosimilar versions of our products have challenged and may continue to challenge our patents well in advance of the expiration of our material patents. For information related to our biosimilars patent litigation, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements. See Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in present and future intellectual property litigation. The U.S. pathway includes the option for biosimilar products that meet certain criteria to be approved as interchangeable with their reference products. Some companies currently developing biosimilars may seek to register their products as interchangeable biologics, which could make it easier for pharmacists to substitute those biosimilars for our products or could encourage prescribers who are inclined to select the interchangeable biosimilar over our innovative products. In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law's provisions regarding which new products receive data exclusivity, which could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, public, legislative, and FDA efforts to promote price competition through easier generic entry. While we are unable to predict the precise impact of biosimilars on our products, we are currently facing and expect to face greater competition in the United States, Europe and elsewhere this year and beyond as a result of biosimilar and generic competition and downward pressure on our product prices and sales. This competition has had and could increasingly have a material adverse effect on our business and results of operations.

Our products face substantial competition.

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

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

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. Challenges to patents may come from potential competitors or from parties other than those who seek to market a potentially-infringing product. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing these

product candidates in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We have been in the past, and are currently and expect to be in the future, involved in patent litigation. These matters have included and may in the future include litigation with manufacturers of products that purport to be biosimilars of certain of our products for patent infringement and for failure to comply with certain provisions of the Biologics Price Competition and Innovation Act, including the requirement to provide 180 days' notice in advance of commercial marketing. A determination made by a court, agency or tribunal concerning infringement, validity, enforceability, injunctive or economic remedy, or the right to patent protection, for example, are typically subject to appellate or administrative review. Upon review, such initial determinations may be afforded little or no deference by the reviewing tribunal and may be affirmed, reversed, or made the subject of reconsideration through further proceedings. A patent dispute or litigation may not discourage a potential violator from bringing the allegedly-infringing product to market prior to a final resolution of the dispute or litigation. The period from inception until resolution of a patent dispute or litigation is subject to the availability and schedule of the court, agency or tribunal before which the dispute or litigation is pending. We may be subject to competition during this

period and may not be able to recover fully from the losses, damages, and harms we incur from infringement by the competitor product even if we prevail. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities, be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Further, under the Hatch-Waxman Act, our products approved by the FDA under the FDCA may be the subject of patent litigation with generics competitors before expiry of the five-year period of data exclusivity provided for under the Hatch-Waxman Act and prior to the expiration of the patents listed for the product. Likewise, our innovative biologic products may be the subject of patent litigation prior to the expiration of our patents and, with respect to competitors seeking approval as a biosimilar or interchangeable version of our products, prior to the 12-year exclusivity period provided under the ACA. In addition, we may face additional patent litigation involving claims that the biosimilar product candidates we are working to develop infringe the patents of other companies that manufacture, market or sell the applicable reference products. While we may attempt to challenge such patents, our efforts may be unsuccessful. For information related to our patent litigation with manufacturers of proposed generic and biosimilar versions of our products, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

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

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

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. However, professional societies, practice management groups, insurance carriers, physicians groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities. Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies, and a growing number of organizations are providing assessments of the value and pricing of pharmaceutical products. These assessments may come from private organizations, such as the Institute for Clinical and Economic Review (ICER), which publish their findings and offer recommendations relating to the products' reimbursement by government and private payers. In addition, government HTA organizations, such as the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom and the Canadian Agency for Drugs and Technologies in Health, make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service impact of new, emerging and existing medicines and treatments. Such HTA organizations may recommend reimbursement for our product for a narrower indication than was approved by applicable regulatory agencies, or may recommend against reimbursement entirely. Such recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could have a material adverse effect on our product sales, business and results of operations. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price of our common stock.

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

Our business is subject to extensive regulation by numerous state and federal government authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in foreign countries to obtain approval from regulatory authorities before we manufacture, market and sell our products. Once our products are approved, the FDA and other U.S. and foreign regulatory agencies have substantial authority to require additional testing and reporting, perform inspections, change product labeling or mandate withdrawals of our products. Failure to comply with applicable regulatory requirements may subject us to administrative and/or judicially imposed sanctions or monetary penalties as well as reputational and other harms. The

sanctions could include the FDA's or foreign regulatory authorities' refusals to approve pending applications, delays in obtaining or withdrawals of approvals, delays or suspensions of clinical trials, warning letters, product recalls or seizures, total or partial suspensions of our operations, injunctions, fines, civil penalties and/or criminal prosecutions. Obtaining and maintaining regulatory approval have been, and will continue to be, increasingly difficult, time-consuming and costly. Legislative bodies or regulatory agencies could enact new laws or regulations, change existing laws or regulations, or change their interpretations of laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products or product candidates. The rate and degree of change in existing laws and regulations and regulatory expectations have accelerated in established markets, and regulatory expectations continue to evolve in emerging markets. We are unable to predict whether and when any further changes to laws or regulatory policies affecting our business could occur, such as changes to

regulations governing manufacturer communications concerning drug products and drug product candidates, and whether such changes could have a material adverse effect on our business and results of operations.

Regulatory authorities may also question the sufficiency for approval of the endpoints we select for our clinical trials. A number of our products and product candidates have been evaluated in clinical trials using surrogate endpoints that measure an effect that is known to correlate with an ultimate clinical endpoint. For example, a therapeutic oncology product candidate may be evaluated for its ability to extend the length of time during and after the treatment that a patient lives without the disease worsening, measured by progression-free survival (PFS). Demonstrating that the product candidate produces a statistically significant improvement in PFS does not necessarily mean that the product candidate will show a statistically significant improvement in overall survival, or the time that the patients remain alive. In the cardiovascular setting, a heart disease therapeutic candidate may be evaluated for its ability to reduce LDL-C levels, as elevated LDL-C level has been a surrogate endpoint for cardiovascular events such as death, heart attack and stroke. The use of surrogate endpoints such as PFS and LDL-C reduction, in the absence of other measures of clinical benefit, may not be sufficient for broad usage or approval even when such results are statistically significant. Regulatory authorities could also add new requirements, such as the completion of enrollment in a confirmatory study or the completion of an outcomes study or a meaningful portion of an outcomes study, as conditions for obtaining approval or obtaining an indication. For example, our initial FDA application for Repatha® sought approval for a broader patient population based on data demonstrating that Repatha® reduced LDL-C levels. However, the FDA initially approved Repatha® in 2015 only for a subset of those patients, citing among other things the absence of positive outcomes data showing that Repatha® prevents cardiovascular events. In December 2017, the FDA granted broader approval of Repatha® to reduce the risk of certain cardiovascular events, and also to be used, alone or in combination with other lipid-lowering therapies, for the treatment of adults with primary hyperlipidemia to reduce LDL-C, only after our large phase 3 outcomes study evaluating the ability of Repatha® to prevent cardiovascular events met its primary composite endpoint and key secondary composite endpoint. See Item 1. Business—Significant Developments. There may also be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to other existing treatment options can be shown. The imposition of additional requirements or our inability to meet them in a timely fashion or at all may delay our clinical development and regulatory filing efforts, delay or prevent us from obtaining regulatory approval for new product candidates or new indications for existing products, or prevent us from maintaining our current labels.

Some of our products have been approved by U.S. and foreign regulatory authorities on a conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, BLINCYTO® received conditional marketing authorization for the treatment of patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL from the EC in November 2015, with full authorization conditioned on demonstrating clinical effectiveness and safety in clinical practice and in a subsequent clinical trial. Regulatory authorities are placing greater focus on monitoring products originally approved on an accelerated or conditional basis and on whether the sponsors of such products have met the conditions of the accelerated or conditional approvals. If we are unable to fulfill the regulators' requirements that were conditions of a product's accelerated or conditional approval and/or if regulators re-evaluate the data or risk-benefit profile of our product, the conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change the product's labeled indications or even withdraw the product from the market.

Safety problems or signals can arise as our products and product candidates are evaluated in clinical trials, including investigator sponsored studies, or as our marketed products are used in clinical practice. We are required to continuously collect and assess adverse events reported to us and to communicate to regulatory agencies these adverse events and safety signals regarding our products. Regulatory agencies periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. In 2012, pharmacovigilance legislation became effective in the EU that enhanced the authority of European regulators to require companies to conduct additional post-approval clinical efficacy and safety studies and increased the requirements on sponsor companies to analyze and evaluate the risk-benefit profiles of their products. Similarly, for our products with approved REMS (see Item 1. Business—Government Regulation—Post-approval Phase), we are required to submit periodic assessment reports to the

FDA to demonstrate that the goals of the REMS are being met. REMS and other risk management programs are designed to ensure that a drug's benefits outweigh the risks, and vary in the elements they contain. If the FDA is not satisfied with the results of the periodic assessment reports we submit for any of our REMS, the FDA may also modify our REMS or take other regulatory actions, such as implementing revised or restrictive labeling. The drug delivery devices approved for use in combination with our products are also subject to regulatory oversight and review for safety and malfunctions. If regulatory agencies determine that we or other parties (including our clinical trial investigators, those operating our patient support programs or licensees of our products) have not complied with the applicable reporting, other pharmacovigilance or other safety or quality assessment requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including fines, marketing authorization withdrawal and other penalties. Our product candidates and marketed products can also be affected by safety problems or signals occurring with respect to products that are similar to ours and that implicate an entire class of products. Further, as a result of clinical trials, including sub-analyses or meta-analyses of earlier clinical trials (a meta-analysis

involves the use of various statistical methods to combine results from previous separate but related studies) performed by us or others, concerns may arise about the sufficiency of the data or studies underlying a product's approved label. Such actual or perceived safety problems or concerns can lead to:

- revised or restrictive labeling for our products, or the potential for restrictive labeling that may result in our decision not to commercialize a product candidate;
- requirement of risk management activities or other regulatory agency compliance actions related to the promotion and sale of our products;
- mandated post-marketing commitments or pharmacovigilance programs for our approved products;
- product recalls of our approved products;
- revocation of approval for our products from the market completely, or within particular therapeutic areas or patient types;
- increased timelines or delays in being approved by the FDA or other regulatory bodies; and/or
- fewer treatments or product candidates being approved by regulatory bodies.

For example, since 2006, when adverse safety results involving ESAs were observed, ESAs continue to be the subject of ongoing review and scrutiny. Reviews by regulatory authorities of the risk-benefit profile of ESAs have resulted in, and may continue to result in, changes to ESA labeling and usage in both the oncology and nephrology clinical settings.

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

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

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

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

- the pathway to regulatory approval or reimbursement for product candidates was uncertain or not well-defined.

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

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

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

Further, to increase the number of patients available for enrollment in our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of locations where our experience conducting clinical trials is more limited, including Russia, India, China, South Korea, the Philippines, Singapore and some Central and South American countries, either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to understand the unique regulatory environments of individual countries. Further, we must ensure the timely production, distribution and delivery of the clinical supply of our product candidates to numerous and varied clinical trial sites. If we fail to adequately manage the design, execution and diverse regulatory aspects of our large and complex clinical trials or to manage the production or distribution of our clinical supply, corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates or could lose our ability to market existing products in certain therapeutic areas or altogether. If we are unable to market and sell our products or product candidates or to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations could be materially and adversely affected.

We rely on independent third-party clinical investigators to recruit patients and conduct clinical trials on our behalf in accordance with applicable study protocols, laws and regulations. Further, we rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations. In some circumstances, we enter into co-development arrangements with other pharmaceutical and medical devices companies that provide for the other company to conduct certain clinical trials for the product we are co-developing. We also may acquire companies that have past or ongoing clinical trials or rights to products or product candidates for which clinical trials have been or are being conducted. These trials may not have been conducted to the same standards as ours; however, once an acquisition has been completed we assume responsibility for the conduct of these trials, including any potential risks and liabilities associated with the past and prospective conduct of those trials. If regulatory authorities determine that we or others, including our licensees or co-development partners, or the independent investigators or vendors selected by us, our co-development partners or by a company we have acquired or from which we have acquired rights to a product or product candidate, have not complied with regulations applicable to the clinical trials, those authorities may refuse or reject some or all of the clinical trial data or take other actions that could negatively impact our ability to obtain or

maintain marketing approval of the product or indication. If we were unable to market and sell our products or product candidates, our business and results of operations could be materially and adversely affected.

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

Clinical trials must be designed based on the current standard of medical care. However, in certain diseases, such as cancer, the standard of care is evolving rapidly. In such diseases, the duration of time needed to complete certain clinical trials may result

in the design of such clinical trials being based on standards of medical care that are no longer the current standards by the time such trials are completed, limiting the utility and application of such trials. We may not obtain favorable clinical trial results and therefore may not be able to obtain regulatory approval for new product candidates or new indications for existing products and/or maintain our current product labels. Participants in clinical trials of our products and product candidates may also suffer adverse medical events or side effects that could, among other factors, delay or terminate clinical trial programs and/or require additional or longer trials to gain approval.

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

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

Many of our products and product candidates may be used in combination with a drug delivery device, such as an injector or other delivery system. For example, Neulasta® is available as part of the Neulasta® Onpro® kit, and we recently launched the AutoTouch™ reusable auto-injector to be used with Enbrel Mini™ single-dose prefilled cartridges. In addition, some of our product candidates may also be used in combination with a companion diagnostic device. Our product candidates or expanded indications of our products used with such devices may not be approved or may be substantially delayed in receiving regulatory approval if such devices do not also gain or maintain regulatory approval or clearance. When approval of the product and device is sought under a single marketing drug application, the increased complexity of the review process may delay receipt of regulatory approval. In addition, some of these devices may be provided by single-source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or clearance by the applicable regulatory agencies. We are also dependent on those third-party companies continuing to meet applicable regulatory or other requirements. Failure to successfully develop or supply the devices, delays in or failures of the Amgen or third-party studies, or failure of us or the third-party companies to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs; delays in, or failure to obtain, regulatory approval; and/or associated delays in a product candidate reaching the market or in the addition of new indications for existing products. We are also required to collect and assess user complaints, adverse events, and malfunctions regarding our devices, and actual or perceived safety problems or concerns with a device used with our product can lead to regulatory actions and impacts to our products. See Our current products and products in development cannot be sold without regulatory approval. Additionally, regulatory agencies conduct routine monitoring and conduct inspections to identify and evaluate potential issues with our devices. For example, in 2017 the FDA reported on its adverse event reporting system that it is evaluating our Neulasta® Onpro® kit. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop, supply, or gain or maintain approval for these devices could adversely affect sales of the related, approved products.

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

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

Our tax returns are routinely examined by tax authorities in the United States and other jurisdictions in which we do business, and a number of audits are currently underway. Tax authorities are becoming more aggressive in their audits and are particularly focused on the allocations of income and expense among tax jurisdictions. As previously disclosed, we received a Revenue Agent Report (RAR) from the Internal Revenue Service (IRS) for the years 2010,

2011, and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. On November 29, 2017, we received a modified RAR that revised their calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution through the IRS administrative appeals process, which we believe will likely not be concluded within the next 12 months. Final resolution of the IRS audit could have a material impact on our results of operations and cash flows if not resolved favorably. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. See Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred

tax assets and liabilities, and changes in applicable tax laws, regulations or administrative interpretations thereof. We incurred a net estimated tax expense of $6.1 billion due to the repatriation tax on accumulated foreign earnings and the remeasurement of certain net deferred and other tax liabilities as a result of the 2017 Tax Act. In computing our expense, we are allowed under new SEC accounting guidance to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We consider a number of key estimates we have made with respect to the 2017 Tax Act to be incomplete due to our continuing analysis of final year-end data and tax positions. Our continuing analysis (which will include evaluation of future U.S. Treasury regulations, accounting interpretations or other developments relating to the 2017 Tax Act) could affect the measurement of these balances and give rise to new deferred tax assets and liabilities. See Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Income taxes.

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

We currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and substantially all of our clinical manufacturing activities at our facility in Thousand Oaks, California. The global supply of our products and product candidates for commercial sales and for use in our clinical trials is significantly dependent on the uninterrupted and efficient operation of these facilities. See Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

In late September 2017, Hurricane Maria made landfall on the island of Puerto Rico. The hurricane destroyed residential and commercial buildings, agriculture, communications networks and most of Puerto Rico's electric grid. The critical manufacturing areas of our commercial manufacturing facility were not significantly impacted by the storm, and we have now resumed our full manufacturing operations. The restoration of electrical service on the island has been a slow process. As a result, our facility operated with electrical power from back-up diesel-powered generators through the end of 2017 and we received regular deliveries of diesel fuel under pre-arranged contracts. In January 2018, we reconnected to the Puerto Rico electric grid and began operating without the back-up generators. However, power has not been restored to the entire island, and it is possible that the electric grid may not remain stable and we may be required to resume use of our diesel generators. In addition, supplies of medical-grade oxygen and nitrogen used in biopharmaceutical manufacturing operations are limited on the island, and we have arranged deliveries of both gases from the U.S. mainland and other countries. See Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

While nearly all of our staff have returned to work, some of them or their families may now or in the future be without housing, access to food and clean water, electricity, healthcare, sanitation, communications services, childcare, transportation or other essentials, and for these or other reasons some of our staff may be forced or elect to temporarily or permanently relocate elsewhere on or off the island. A substantial disruption in our ability to operate our Puerto Rico manufacturing facility (whether due to problems with the facility itself, the infrastructure and services available on the island, the unavailability of raw materials or supplies from vendors, the unavailability of key staff or otherwise) or get supplies and manufactured products transported to and from that location could materially and adversely affect our ability to supply our products and affect our product sales. See Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

The impact of Hurricane Maria is certain to place greater stress on the island's already challenged economy. Since June 2015, when the Governor of Puerto Rico announced that the government (including certain government entities) was unable to pay its roughly $72 billion in debt, the government's liquidity position has continued to deteriorate and public reports indicate that the Puerto Rico government is not making certain payments with respect to its obligations. On June 30, 2016, President Obama signed into law the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA) to provide a mechanism for Puerto Rico to restructure its debt, achieve fiscal responsibility and gain access to capital markets. PROMESA established a federal Financial Oversight and Management Board (Oversight Board) to provide fiscal oversight through the development and approval of fiscal plans and budgets for Puerto Rico and to assist in the debt restructuring. In May 2017, after negotiations with creditors were unsuccessful and an

automatic stay of creditor actions expired, the Oversight Board approved and certified the filing in the U.S. District Court for the District of Puerto Rico of a voluntary petition under Title III of PROMESA for the government of Puerto Rico, following thereafter with similar filings for certain Puerto Rico government entities. Title III of PROMESA provides Puerto Rico with a judicial process for restructuring its debt similar to, but not identical to, Chapter 9 of the U.S. Bankruptcy Code. Given the severe conditions in Puerto Rico after Hurricane Maria, it is expected that resolution of Puerto Rico's outstanding debt situation through the PROMESA judicial process will be delayed pending recovery efforts. Additionally, in January 2017, the Puerto Rico government enacted the Puerto Rico Fiscal Emergency and Fiscal Responsibility Act, which, among other things, declared a state of financial emergency in Puerto Rico and authorized the Governor to designate certain services as essential services, and other services as non-essential in order to prioritize the use of available resources to satisfy Puerto Rico's obligations. The Puerto Rico government has continued to extend the emergency period. In June 2017, the Oversight Board certified the Puerto Rico government's budget for fiscal year 2018. In January 2018, the Puerto Rico government proposed a revised fiscal plan. The revised fiscal plan

is subject to approval by the Oversight Board and calls for delayed and reduced payments to creditors and assumes U.S. federal disaster assistance of $35 billion.

The Puerto Rico government is continuing to seek assistance from the U.S. government for disaster relief related to Hurricane Maria. In October 2017, the U.S. Congress approved a supplemental appropriation for disaster relief whereby Puerto Rico could receive a loan of up to approximately $5 billion to be used by the Puerto Rico government to provide essential services. U.S. and Puerto Rico officials are currently negotiating the terms and conditions of disaster relief loans that may be granted to Puerto Rico. In November 2017, the Governor of Puerto Rico submitted an additional request for federal disaster assistance to restore housing and rebuild a resilient power grid. It is not certain whether and what amounts will be appropriated by the U.S. Congress to assist in the hurricane recovery. In addition, the recently enacted U.S. tax reform legislation will no longer permit deferral of U.S. taxation on Puerto Rico earnings of U.S. companies (or their foreign subsidiaries), although these earnings generally will be taxed in the United States at a reduced 10.5% rate. Given Puerto Rico's challenged economy and hurricane recovery needs, it may be difficult for Puerto Rico to sustain or grow its manufacturing base due to competition from other foreign locations subject to a similar level of U.S. taxation, or U.S. locations due to the reduction in the U.S. corporate tax rate from 35% to 21%. The manufacturing sector currently contributes more than 45% of Puerto Rico's gross domestic product, and U.S. companies with Puerto Rico operations contribute more than 33% of Puerto Rico's revenue base.

While PROMESA and the actions above continue to be important factors in moving Puerto Rico toward economic stability, there is still a risk that Puerto Rico's ongoing economic challenges, the effects of Hurricane Maria and the potential impact of the 2017 Tax Act could negatively affect the territorial government's provision of utilities or other services in Puerto Rico that we use in the operation of our business, create the potential for increased taxes or fees to operate in Puerto Rico, result in a migration of workers from Puerto Rico to the mainland United States, and/or make it more expensive or difficult for us to operate in Puerto Rico, which could materially and adversely affect our ability to supply our products and affect our product sales.

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

We rely on unaffiliated third-party suppliers for certain raw materials, medical devices and components necessary for the manufacturing of our commercial and clinical products. Certain of those raw materials, medical devices and components are proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug applications with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until the regulatory agency approved such supplier. For example, Insulet Corporation is our single source of the on-body injector for our Neulasta® Onpro® kit. Also, certain of the raw materials required in the commercial and clinical manufacturing of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues, bovine serum and human serum albumin. Among the reasons we may be unable to obtain these raw materials, medical devices and components include:

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

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

Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales. Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. We currently are involved in the manufacture of many of our products and plan to manufacture many of our product candidates. In addition, we currently use third-party contract manufacturers to produce, or assist in the production of, a number of our products, and we currently use

contract manufacturers to produce, or assist in the production of, a number of our late-stage product candidates and drug delivery devices. See Item 1. Business—Manufacturing, Distribution and Raw Materials—Manufacturing. Our ability to adequately and timely manufacture and supply our products and product candidates is dependent on the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers, which may be impacted by:

- capacity of manufacturing facilities;
- contamination by microorganisms or viruses, or foreign particles from the manufacturing process;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of health emergencies or natural disasters;
- compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs and production success rates and yields;
- updates of manufacturing specifications;
- contractual disputes with our suppliers and contract manufacturers;
- timing and outcome of product quality testing;
- power failures and/or other utility failures; and/or
- breakdown, failure, substandard performance or improper installation or operation of equipment.

If the efficient manufacture and supply of our products or product candidates is interrupted, we may experience delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends, contract disputes and/or recalls of our products. From time to time we have initiated voluntary recalls of certain lots of our products. For example, in July 2014, we initiated a voluntary recall of an Aranesp® lot distributed in the EU after particles were detected in a quality control sample following distribution of that lot. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could have a material adverse effect on our product sales, business and results of operations.

Our manufacturing processes and those of our third-party contract manufacturers must undergo regulatory approval processes and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build, validate and license another manufacturing plant and it can take longer than three years to qualify and license a new contract manufacturer. We are in the process of commercially validating and licensing a second facility at our site in Singapore to enable the manufacture of the active pharmaceutical ingredient for KYPROLIS®. If we are unable to obtain needed licenses for this facility on a timely basis, it could adversely affect our ability to achieve our planned risk mitigation and cost reductions which, as a result, could have a material adverse effect on our product sales, business and results of operations.

If regulatory authorities determine that we or our third-party contract manufacturers or certain of our third-party service providers have violated regulations or if authorities restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. Such issues may also delay the approval of product candidates we have submitted for regulatory review, even if such product candidates are not directly related to the products, devices or processes at issue with regulators. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis or at all. If we or our third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers fail to supply materials, products or services to us, we may experience delayed shipments, delays in our clinical trials, supply constraints, contract disputes, stock-outs and/or recalls of our products. Additionally, we distribute a substantial volume of our commercial products through our primary distribution centers in Louisville, Kentucky for the United States and in Breda, Netherlands for Europe and much of the rest of the world. We also conduct all the labeling and packaging of our products distributed in Europe and much of the rest of the world in Breda. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics

centers, our third-party logistics providers and our labeling and packaging facility in Breda. Further, we rely on commercial transportation, including air freight, for the distribution of our products to our customers, which may be negatively impacted by natural disasters or security threats.

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

Certain of our distributors, customers and payers have substantial purchasing leverage, due to the volume of our products they purchase or the number of patient lives for which they provide coverage. The substantial majority of our U.S. product sales is made to three pharmaceutical product wholesaler distributors: AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc. These distributors, in turn, sell our products to their customers, which include physicians or their clinics, dialysis centers, hospitals and pharmacies. One of our products, EPOGEN®, is sold primarily to free-standing dialysis clinics. DaVita owns or manages a large number of the outpatient dialysis facilities located in the United States and accounts for approximately 70% of all EPOGEN® sales. Similarly, as discussed above, there has been significant consolidation in the health insurance industry, including that a small number of PBMs now oversee a substantial percentage of total covered lives in the United States. See Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability. The concentration of purchasing and negotiating power by these entities may put pressure on our pricing due to their ability to extract price discounts on our products, fees for other services or rebates, negatively impacting our bargaining position, sales and/or profit margins. In addition, decisions by these entities to purchase or cover less or none of our products in favor of competitive products could have a material adverse effect on our business and results of operations due to their purchasing volume. Further, if one of our significant wholesale distributors encounters financial or other difficulties and becomes unable or unwilling to pay us all amounts that such distributor owes us on a timely basis or at all, it could negatively impact our business and results of operations. In addition, if one of our significant wholesale distributors becomes insolvent or otherwise unable to continue its commercial relationship with us in its present form, it could significantly disrupt our business and adversely affect our product sales, our business and results of operations unless suitable alternatives are timely found or lost sales are absorbed by another distributor.

Our efforts to acquire other companies or products and to integrate their operations may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.

We seek innovation through significant investment in both internal R&D and external transactions including collaborations, partnering, alliances, licenses, joint ventures, mergers and acquisitions (acquisition activity). We have an ongoing process of evaluating such potential acquisition activity opportunities that we expect will contribute to our future growth and expand our geographic footprint, product offerings and/or our R&D pipeline. Acquisitions or similar arrangements may be complex, time consuming and expensive and may result in unanticipated costs, delays or other operational or financial problems related to integrating the acquired company and business with our company, which may result in the diversion of our management’s attention from other business issues and opportunities. We may pay substantial amounts of cash, incur debt or issue equity securities to pay for acquisition activities, which could adversely affect our liquidity or result in dilution to our stockholders, respectively. Failures or difficulties in integrating or retaining new personnel or in integrating the operations of the businesses we acquire (including their technology, compliance programs, distribution and general business operations and procedures), while preserving important R&D, distribution, marketing, promotion and other relationships, may affect our ability to grow and may result in our incurring asset impairment or restructuring charges.

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

As we continue our expansion efforts in emerging markets around the world, through acquisitions and licensing transactions as well as through the development and introduction of our products in new markets, we face numerous risks to our business. There is no guarantee that our efforts and strategies to expand sales in emerging markets will succeed. Emerging market countries may be especially vulnerable to periods of global political, legal, regulatory and financial instability, including sovereign debt issues and/or the imposition of international sanctions in response to certain state actions. As we expand internationally, we are subject to fluctuations in foreign currency exchange rates relative to the U.S. dollar. While we have a program in place that is designed to reduce our exposure to foreign currency exchange rate fluctuations through foreign currency hedging arrangements, our hedging efforts do not completely offset the effect of these fluctuations on our revenues and earnings. We may also be required to increase our reliance on third-party agents and unfamiliar operations and arrangements previously utilized by companies we

partner with or acquire in emerging markets. See We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications. Our international operations and business may also be subject to less protective intellectual property or other applicable laws, diverse data privacy and protection requirements, changing tax laws and tariffs, far-reaching anti-bribery and anti-corruption laws and regulations and/or evolving legal and regulatory environments. These legal and operational challenges along with government controls, the challenges of attracting and retaining qualified personnel and obtaining and/or maintaining necessary regulatory or pricing approvals of our products may result in a material adverse impact on our international product sales, business and results of operations.

Our business may be affected by litigation and government investigations.

We and certain of our subsidiaries are involved in legal proceedings. See Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements. Civil and criminal litigation is inherently unpredictable, and the outcome can result in

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

We are also involved in government investigations that arise in the ordinary course of our business. In recent years, there has been a trend of increasing government investigations and litigations against companies operating in our industry, both in the United States and around the world. Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. As we announced on December 19, 2012, we finalized a settlement agreement with the U.S. government and various other parties to settle certain allegations regarding our sales and marketing practices. In connection with that settlement, we have been operating under a corporate integrity agreement with the OIG of the U.S. Department of Health and Human Services that requires us to maintain our corporate compliance program and to undertake a set of defined corporate integrity obligations until December 2017. The corporate integrity agreement also provides for an independent third-party review organization to assess and report on our compliance program. Certain of the corporate integrity agreement's reporting obligations to OIG continue into 2018. While we expect to fully comply with all of our obligations under the corporate integrity agreement, failure to do so could result in substantial penalties and our being excluded from government healthcare programs. We may see new government investigations of or actions against us citing novel theories of recovery. Any of these results could have a material adverse effect on our business and results of operations.

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

To achieve our business objectives, we rely to a large extent upon sophisticated information technology systems and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or affect our reputation.

Our information technology systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. The complexity and interconnected nature of our systems makes them potentially vulnerable to breakdown or other service interruptions. Our systems are also subject to frequent cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering and/or other means. Attacks such as those recently seen with other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access important data needed to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and distributing our products. For example, in 2017, Merck experienced a cyberattack involving virulent malware that significantly disrupted its operations, including the production of some of its medicines and vaccines. Our systems also contain and utilize a high volume of sensitive data, including intellectual property, trade secrets, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials or personal information belonging to us, our staff, our patients, customers and/or other business partners. In some cases, we utilize third-party service providers to manage or transmit such data, which may increase our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) by employees, service providers, nation states, organized crime organizations, "hacktivists" or others, pose risks that our sensitive data may be exposed to unauthorized persons, our competitors, or the public. Finally, domestic and global

government regulators, our key business partners, suppliers with whom we do business, companies that provide us or our partners with important business services and companies we may acquire may face similar risks, and security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. For example, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers.

Although in the past we have experienced system breakdowns, attacks and information security breaches, we do not believe such breakdowns, attacks and breaches have had a material adverse effect on our operations. We continue to invest in the monitoring, protection, and resilience of our critical or sensitive data and systems. However, there can be no assurance that our efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks, or breaches of our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data, which could result in

financial, legal, business or reputational harm to us or impact our stock price. While we maintain cyber-liability insurance, our insurance is not sufficient to cover us against all losses that could potentially result from a service interruption, breach of our systems or loss of our critical or sensitive data.

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

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

We maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our Consolidated Balance Sheets. The value of our investments may be adversely affected by interest rate fluctuations, downgrades in credit ratings, illiquidity in the capital markets and other factors that may result in other-than-temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on sales of investments.

Our stock price is volatile.

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

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

The capital and credit markets may experience extreme volatility and disruption which may lead to uncertainty and liquidity issues for both borrowers and investors. We expect to access the capital markets to supplement our existing funds and cash generated from operations in satisfying our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. In the event of adverse capital and credit market conditions, we may be unable to obtain capital market financing on similar favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Changes in credit ratings issued by nationally recognized credit-rating agencies could adversely affect our ability to obtain capital market financing and the cost of such financing and have an adverse effect on the market price of our securities.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

As of December 31, 2017, we owned or leased approximately 180 properties. The locations and primary functions of significant properties are summarized in the following tables:

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

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

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

Item 3. LEGAL PROCEEDINGS

Certain of the legal proceedings in which we are involved are discussed in Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements, and are hereby incorporated by reference.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Common stock

Our common stock trades on the NASDAQ Global Select Market under the symbol AMGN. As of February 9, 2018, there were approximately 6,070 holders of record of our common stock.

The following table sets forth, for the periods indicated, the range of high and low quarterly closing sales prices of the common stock as quoted on the NASDAQ Global Select Market:

Year ended December 31, 2017	High	Low
Fourth quarter	$188.59	$168.79
Third quarter	$191.00	$167.29
Second quarter	$174.07	$153.02
First quarter	$182.60	$150.73
Year ended December 31, 2016		
Fourth quarter	$168.31	$135.22
Third quarter	$175.62	$154.27
Second quarter	$164.35	$144.58
First quarter	$158.34	$140.90

Performance graph

The following graph shows the value of an investment of $100 on December 31, 2012, in each of Amgen common stock, the Amex Biotech Index, the Amex Pharmaceutical Index and Standard & Poor's 500 Index (S&P 500). All values assume reinvestment of the pretax value of dividends and are calculated as of December 31 of each year. The historical stock price performance of the Company's common stock shown in the performance graph is not necessarily indicative of future stock price performance.

Amgen vs. Amex Biotech, Amex Pharmaceutical and S&P 500 Indices

Comparison of Five-Year Cumulative Total Return

Value of Investment of $100 on December 31, 2012

	12/31/2012	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017
Amgen (AMGN)	$100.00	$134.52	$191.45	$199.05	$184.03	$225.10
Amex Biotech (BTK)	$100.00	$150.77	$223.02	$248.42	$200.85	$276.79
Amex Pharmaceutical (DRG)	$100.00	$131.22	$152.97	$159.36	$146.07	$170.36
S&P 500 (SPX)	$100.00	$132.04	$150.11	$152.17	$170.36	$207.65

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

Stock repurchase program

During the three months and year ended December 31, 2017, we had one outstanding stock repurchase program, under which the repurchasing activity was as follows:

	Total number of shares purchased	Average price paid per share[1]	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program[2]
October 1 - October 31	1,315,799	$ 181.90	1,315,799	$3,420,112,053
November 1 - November 30	1,851,275	$ 171.44	1,851,275	$4,609,000,103
December 1 - December 31	1,354,857	$ 176.55	1,354,857	$4,369,804,885
	4,521,931	$ 176.01	4,521,931	
January 1 - December 31	18,528,595	$ 168.71	18,528,595	

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

(2) In October 2017, our Board of Directors authorized an increase that resulted in a total of $5.0 billion available under our stock repurchase program. In January 2018, our Board of Directors authorized an additional $10.0 billion under our stock repurchase program.

Dividends

For the years ended December 31, 2017 and 2016, we paid quarterly dividends. We expect to continue to pay quarterly dividends, although the amount and timing of any future dividends are subject to approval by our Board of Directors. Additional information required by this item is incorporated herein by reference to Part IV—Note 15, Stockholders' equity, to the Consolidated Financial Statements.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

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

Item 6. SELECTED FINANCIAL DATA

	Years ended December 31,				
Consolidated Statements of Income Data:	2017	2016	2015	2014	2013
	(In millions, except per share data)				
Revenues:					
Product sales	$21,795	$21,892	$20,944	$19,327	$18,192
Other revenues	1,054	1,099	718	736	484
Total revenues	$22,849	$22,991	$21,662	$20,063	$18,676
Operating expenses:					
Cost of sales	$4,069	$4,162	$4,227	$4,422	$3,346
Research and development	$3,562	$3,840	$4,070	$4,297	$4,083
Selling, general and administrative	$4,870	$5,062	$4,846	$4,699	$5,184
Net income[1]	$1,979	$7,722	$6,939	$5,158	$5,081
Diluted earnings per share[1]	$2.69	$10.24	$9.06	$6.70	$6.64
Dividends paid per share	$4.60	$4.00	$3.16	$2.44	$1.88
	As of December 31,				
Consolidated Balance Sheets Data:	2017	2016	2015	2014	2013
	(In millions)				
Total assets	$79,954	$77,626	$71,449	$68,882	$65,974
Total debt[2]	$35,342	$34,596	$31,429	$30,588	$31,977
Total stockholders' equity[3]	$25,241	$29,875	$28,083	$25,778	$22,096

In addition to the following notes, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and the Consolidated Financial Statements and accompanying notes and previously filed Annual Reports on Form 10-K for further information regarding our consolidated results of operations and financial position for periods reported therein and for known factors that will affect the comparability of future results. Also, see Part IV—Note 15, Stockholders' equity, to the Consolidated Financial Statements, for information regarding cash dividends declared per share of common stock for each of the four quarters of 2017, 2016, and 2015, respectively. In addition, our Board of Directors declared dividends per share of $0.61 and $0.47 that were paid in each of the four quarters of 2014 and 2013, respectively.

(1) In 2017, we recorded a net charge of $6.1 billion as a result of the 2017 Tax Act. See Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

(2) See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements, for discussion of our financing arrangements. In 2014, we issued $4.5 billion of debt and repaid $5.6 billion of debt. In 2013, we issued $8.1 billion of debt and repaid of $3.4 billion of debt.

(3) Throughout the five years ended December 31, 2017, we had a stock repurchase program authorized by the Board of Directors through which we repurchased $3.1 billion, $3.0 billion, $1.9 billion, $0.2 billion and $0.8 billion, respectively, of Amgen common stock.

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

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

Forward-looking statements

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

Overview

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

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

Six therapeutic areas form the core of our business—oncology/hematology, cardiovascular disease, inflammation, bone health, nephrology and neuroscience. Our strategy to execute in these therapeutic areas is multifaceted as we engage in a series of integrated activities to strengthen our competitive position in the industry focused on seven strategic priorities:

In 2017, we made substantial progress on our strategic priorities.

- Our innovative pipeline continued to advance with the addition of cardiovascular outcomes data to the Repatha® label in the United States. The FDA also approved Parsabiv™ for secondary hyperparathyroidism in hemodialysis patients and Vectibix®, in combination with chemotherapy, for use in wild-type RAS metastatic colorectal cancer, and expanded the BLINCYTO® indication to include the treatment of relapsed or refractory B-cell precursor ALL in adults and children. We submitted the U.S. regulatory filing for Aimovig™ for the prevention of migraine in patients experiencing four or more migraines per month. We also made U.S. and EU regulatory filings to include overall survival data in the KYPROLIS® label for relapsed or refractory multiple myeloma patients and to expand the XGEVA® indication to include the prevention of SREs in patients with multiple myeloma. We announced positive phase 3 results for a weekly regimen of KYPROLIS® for the treatment of relapsed or refractory multiple myeloma and positive phase 2b results with tezepelumab, which has now advanced into Phase 3 for the treatment of severe, uncontrolled asthma. Throughout the course of the year, we invested in external early-stage innovation to augment our internal research efforts.
- Our biosimilars also continued to advance as the FDA approved MVASI™ for the treatment of five types of cancer, and the EC approved AMGEVITA™ for the treatment of certain inflammatory diseases. We also gained clarity on the launch timing of AMGEVITA,™ which is now expected in Europe later this year and we submitted U.S. and EU regulatory filings for ABP 980.
- We continued to build the foundation for long-term growth through our product launches in new parts of the world, as seen by our ability to secure 80 country product launches, leveraging our global presence to deliver the potential of our products to patients.

- We continued to provide an uninterrupted supply of medicines for patients around the world while responding to natural disasters and investing for the future.
  - In September 2017, Hurricane Maria made landfall on the island of Puerto Rico. The hurricane caused widespread damage to the island, however, the critical manufacturing areas of our site in Juncos were not significantly impacted and we have resumed our full manufacturing operations.
  - We made investments in next-generation biomanufacturing that build on our expertise in human biology and protein manufacturing. This next-generation biomanufacturing dramatically reduces the scale and costs of making biologics while retaining a reliable, high-quality, compliant supply of medicines. In 2017, our new Singapore facility that uses our next-generation biomanufacturing technology was approved for certain commercial production by multiple regulatory agencies, including the FDA and the EMA.
- We continued to innovate with delivery systems to differentiate our products, as seen by our development of the AutoTouch™ reusable auto-injector to be used with Enbrel Mini™ single-dose prefilled cartridges (50 mg/mL), which was approved by the FDA in September 2017. This device was ergonomically designed to meet the needs of rheumatoid arthritis patients. We also launched our Repatha® automated mini-doser with pre-filled cartridge in Europe. This hands-free device provides Repatha® in a single injection for administration monthly. Further, the use of the Neulasta® Onpro® On-body Injector continues to increase, exiting 2017 with over 60% share of Neulasta® sales.
- Cash flows from operating activities grew 8% to $11.2 billion, enabling us to invest for the future and return capital to shareholders, consistent with our expectations for long-term growth. We increased our dividend 15% to $1.15 per share of common stock in each of the four quarters of 2017. In December 2017, the Board of Directors declared a cash dividend of $1.32 per share of common stock for the first quarter of 2018, an increase of 15% for this period, to be paid in March 2018. We also repurchased 18.5 million shares of our common stock throughout 2017 at an aggregate cost of $3.1 billion.
- We further optimized our business and operating model through significant transformation and process improvement efforts. Our transformation has established a foundation for growth and we are approaching the development of promising new medicines with greater understanding, speed and confidence.

Our 2017 financial results also reflect the impact of the 2017 Tax Act. We now have global access to our $41.7 billion balance of cash, cash equivalents and marketable securities, which unlocks additional financial flexibility.

While 2017 execution was strong, we expect 2018 will be another important year as we continue to invest in the pipeline, build our global business and support new product growth. In preparation for 2018, we expanded our transformation activities and savings initiatives to enable investment in new products and the defense of existing products to optimize long- and short-term growth. Our long-term success depends, to a great extent, on our ability to continue to discover, develop and commercialize innovative products and acquire or collaborate on therapies currently in development by other companies. We must develop new products over time in order to provide for revenue growth and to offset revenue losses when products lose their exclusivity or competing products are launched. Certain of our products will face increasing pressure from competition, including biosimilars and generics. For additional information, including information on the expiration of patents for various products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents and see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We devote considerable resources to R&D activities. However, successful product development in the biotechnology industry is highly uncertain. We are also confronted by increasing regulatory scrutiny of safety and efficacy both before and after products launch.

Rising healthcare costs and economic conditions also continue to pose challenges to our business, including continued pressure by third-party payers, such as governments and private payers, to reduce healthcare expenditures. As a result of public and private health care provider focus, the industry continues to experience significant pricing pressures and other cost containment measures.

Finally, wholesale and end-user buying patterns can affect our product sales. These effects can cause fluctuations in quarterly product sales and have generally not been significant when comparing full-year product performance to the prior year. See Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products and Part I, Item 1A. Risk Factors for further discussion of certain of the factors that could impact our future product sales.

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Selected Financial Information

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

	Year ended December 31, 2017	Change	Year ended December 31, 2016
Product sales:			
U.S.	$ 17,131	(1)%	$ 17,325
Rest of world (ROW)	4,664	2 %	4,567
Total product sales	21,795	— %	21,892
Other revenues	1,054	(4)%	1,099
Total revenues	$ 22,849	(1)%	$ 22,991
Operating expenses	$ 12,876	(2)%	$ 13,197
Operating income	$ 9,973	2 %	$ 9,794
Net income	$ 1,979	(74)%	$ 7,722
Diluted EPS	$ 2.69	(74)%	$ 10.24
Diluted shares	735	(3)%	754

In the following discussion of changes in product sales, any reference to unit demand growth or decline refers to changes in the purchases of our products by healthcare providers, such as physicians or their clinics, dialysis centers, hospitals and pharmacies.

Total product sales for 2017 decreased slightly as a decline in U.S. product sales was offset partially by an increase in ROW product sales. The U.S. decrease was driven primarily by lower unit demand resulting from competition, offset partially by increases in net selling prices and favorable changes in inventory. The increase in ROW product sales for 2017 was driven primarily by higher unit demand, offset partially by unfavorable changes in foreign exchange rates and declines in net selling prices.

Operating expenses for 2017 decreased 2%. All expense categories benefited from savings resulting from our transformation and process improvement efforts.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is offset partially by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material in 2017, 2016 or 2015.

Results of Operations

Product sales

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

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
ENBREL	$ 5,433	(9)%	$ 5,965	11 %	$ 5,364
Neulasta®	4,534	(2)%	4,648	(1)%	4,715
Aranesp®	2,053	(2)%	2,093	7 %	1,951
Prolia®	1,968	20 %	1,635	25 %	1,312
Sensipar®/Mimpara®	1,718	9 %	1,582	12 %	1,415
XGEVA®	1,575	3 %	1,529	9 %	1,405
EPOGEN®	1,096	(15)%	1,282	(31)%	1,856
Other products	3,418	8 %	3,158	8 %	2,926
Total product sales	$ 21,795	— %	$ 21,892	5 %	$ 20,944
Total U.S.	$ 17,131	(1)%	$ 17,325	5 %	$ 16,523
Total ROW	4,664	2 %	4,567	3 %	4,421
Total product sales	$ 21,795	— %	$ 21,892	5 %	$ 20,944

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

ENBREL

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

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
ENBREL — U.S.	$ 5,206	(9)%	$ 5,719	12 %	$ 5,099
ENBREL — Canada	227	(8)%	246	(7)%	265
Total ENBREL	$ 5,433	(9)%	$ 5,965	11 %	$ 5,364

The decrease in ENBREL sales for 2017 was driven primarily by lower unit demand and net selling price, offset partially by an increase in inventory. For 2018, we expect the trends of lower unit demand and net selling price to continue.

The increase in ENBREL sales for 2016 was driven primarily by an increase in net selling price, offset partially by the impact of competition.

Neulasta®

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

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
Neulasta® — U.S.	$ 3,931	— %	$ 3,925	1 %	$ 3,891
Neulasta® — ROW	603	(17)%	723	(12)%	824
Total Neulasta®	$ 4,534	(2)%	$ 4,648	(1)%	$ 4,715

The decreases in global Neulasta® sales for 2017 and 2016 were driven primarily by lower unit demand, offset partially by an increase in net selling price in the United States. As of the end of December 2017, utilization of the

Neulasta® Onpro® kit continues to grow in the United States.

Our final material U.S. patent for Neulasta® expired in October 2015. Therefore, we expect to face competition in the United States, which over time may have a material adverse impact on future sales of Neulasta®. Multiple companies have announced applications to the FDA for proposed biosimilar versions of Neulasta®. While a number of these companies have announced receipt of Complete Response Letters from the FDA regarding their applications, certain of these companies may receive approval in 2018. For discussion of ongoing patent litigations with these and other companies developing proposed biosimilar versions of Neulasta®, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

In addition, supplementary protection certificates issued by certain countries, including France, Germany, Italy, Spain and the United Kingdom, relating to our European patent for Neulasta® expired in August 2017. For further information regarding our patents, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents.

Neulasta® sales have been and will continue to be impacted by the development of new protocols, tests and/or treatments for cancer and/or new treatment alternatives that have reduced and may continue to reduce the use of myelosuppressive regimens in some patients.

Aranesp®

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

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
Aranesp® — U.S.	$ 1,114	3 %	$ 1,082	20 %	$ 900
Aranesp® — ROW	939	(7)%	1,011	(4)%	1,051
Total Aranesp®	$ 2,053	(2)%	$ 2,093	7 %	$ 1,951

The decrease in global Aranesp® sales for 2017 was driven primarily by unfavorable changes in foreign currency exchange rates, offset partially by higher unit demand, including a shift of some U.S. dialysis centers from EPOGEN®.

The increase in global Aranesp® sales for 2016 was driven primarily by higher unit demand, including a shift of some U.S. dialysis centers from EPOGEN®, offset partially by a decrease in net selling price in ROW.

For 2018, we expect Aranesp® to face increasing competition from branded products. We could also face competition from biosimilar versions of EPOGEN® in 2018 if they launch in the United States.

Prolia®

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

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
Prolia® — U.S.	$ 1,272	21 %	$ 1,049	25 %	$ 837
Prolia® — ROW	696	19 %	586	23 %	475
Total Prolia®	$ 1,968	20 %	$ 1,635	25 %	$ 1,312

The increases in global Prolia® sales for 2017 and 2016 were driven primarily by higher unit demand.

Sensipar®/Mimpara®

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

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
Sensipar® — U.S.	$ 1,374	11 %	$ 1,240	16 %	$ 1,069
Sensipar®/Mimpara® — ROW	344	1 %	342	(1)%	346
Total Sensipar®/Mimpara®	$ 1,718	9 %	$ 1,582	12 %	$ 1,415

The increases in global Sensipar®/Mimpara® sales for 2017 and 2016 were driven primarily by an increase in net selling price in the United States and, to a lesser extent, higher unit demand.

Our U.S. composition of matter patent relating to Sensipar®, a small molecule, expires in March 2018. We are also involved in a number of litigation matters relating to Sensipar®, including patent litigations with a number of companies seeking to market generic versions of Sensipar® and litigation regarding our request for pediatric exclusivity for Sensipar®. See Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

XGEVA®

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

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
XGEVA® — U.S.	$ 1,157	4 %	$ 1,115	11 %	$ 1,006
XGEVA® — ROW	418	1 %	414	4 %	399
Total XGEVA®	$ 1,575	3 %	$ 1,529	9 %	$ 1,405

The increases in global XGEVA® sales for 2017 and 2016 were driven primarily by higher unit demand.

EPOGEN®

Total EPOGEN® sales were as follows (dollar amounts in millions):

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
EPOGEN® — U.S.	$ 1,096	(15)%	$ 1,282	(31)%	$ 1,856

The decrease in EPOGEN® sales for 2017 was driven primarily by a decline in net selling price due to contractual terms negotiated with DaVita (see Part I, Item 1. Business—Business Relationships) and, to a lesser extent, a shift in some U.S. dialysis centers to Aranesp®.

The decrease in EPOGEN® sales for 2016 was driven by a decline in unit demand resulting from competition and a shift in some U.S. dialysis centers to Aranesp®.

Our final material U.S. patent for EPOGEN® expired in May 2015. We face competition in the United States, which has had, and will continue to have, a material adverse impact on sales of EPOGEN®. Multiple companies are developing proposed biosimilar versions of EPOGEN® and certain of these companies may receive approval in 2018. For discussion of ongoing patent litigation with this company, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

Other products

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

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
KYPROLIS® — U.S.	$ 562	1 %	$ 554	19 %	$ 467
KYPROLIS® — ROW	273	98 %	138	*	45
Vectibix® — U.S.	251	10 %	229	12 %	204
Vectibix® — ROW	391	2 %	382	11 %	345
Nplate® — U.S.	392	12 %	350	10 %	317
Nplate® — ROW	250	7 %	234	13 %	208
NEUPOGEN® — U.S.	369	(31)%	534	(33)%	793
NEUPOGEN® — ROW	180	(22)%	231	(10)%	256
Repatha® — U.S.	225	*	101	*	7
Repatha® — ROW	94	*	40	*	3
BLINCYTO® — U.S.	114	34 %	85	27 %	67
BLINCYTO® — ROW	61	*	30	*	10
Other — U.S.	68	13 %	60	*	10
Other — ROW	188	(1)%	190	(2)%	194
Total other product sales	$ 3,418	8 %	$ 3,158	8 %	$ 2,926
Total U.S. — other products	$ 1,981		$ 1,913		$ 1,865
Total ROW — other products	1,437		1,245		1,061
Total other product sales	$ 3,418		$ 3,158		$ 2,926

* Change in excess of 100%

Operating expenses

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

	Year ended December 31, 2017	Change	Year ended December 31, 2016	Change	Year ended December 31, 2015
Operating expenses:					
Cost of sales	$ 4,069	(2)%	$ 4,162	(2)%	$ 4,227
% of product sales	18.7 %		19.0 %		20.2 %
% of total revenues	17.8 %		18.1 %		19.5 %
Research and development	$ 3,562	(7)%	$ 3,840	(6)%	$ 4,070
% of product sales	16.3 %		17.5 %		19.4 %
% of total revenues	15.6 %		16.7 %		18.8 %
Selling, general and administrative	$ 4,870	(4)%	$ 5,062	4 %	$ 4,846
% of product sales	22.3 %		23.1 %		23.1 %
% of total revenues	21.3 %		22.0 %		22.4 %
Other	$ 375	*	$ 133	*	$ 49

* Change in excess of 100%

Transformation and process improvement

During 2014, we announced transformation and process improvement efforts that we continue to execute. As part of these efforts, we committed to a more agile and efficient operating model. Our transformation and process improvement efforts across the Company are enabling us to reallocate resources to fund many of our innovative pipeline and growth opportunities that deliver value to patients and stockholders.

The transformation includes a restructuring plan that we continue to estimate will result in pre-tax accounting charges in the range of $825 million to $900 million. As of December 31, 2017, restructuring costs incurred to date were $797 million. During 2017, 2016 and 2015, we incurred restructuring costs of $88 million, $37 million and $114 million, respectively. We expect that we will incur most of the remaining estimated costs in 2018 in order to support our ongoing transformation and process improvement efforts. Since 2014, we have realized approximately $1.5 billion of transformation and process improvement savings. Net savings have not been significant as savings were reinvested in product launches, clinical programs and external business development. Additional information required for our restructuring plan is incorporated herein by reference to Part IV—Note 2, Restructuring, to the Consolidated Financial Statements.

Puerto Rico operations

In September 2017, Hurricane Maria made landfall on the island of Puerto Rico. The hurricane caused widespread damage to the island and some damage to our facility in Juncos. Critical manufacturing areas of our facility were not significantly affected, and we have resumed our full manufacturing operations. Further recovery efforts on the island are ongoing. We have continued to provide an uninterrupted supply of medicines for patients around the world. See Part I, Item 1A. Risk Factors—We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and substantially all of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.

We incurred $146 million of pre-tax expenses in 2017 related to Hurricane Maria. At this time, we do not expect significant pre-tax expenses in 2018.

Cost of sales

Cost of sales decreased to 17.8% of total revenues for 2017, driven primarily by lower amortization of intangible assets, lower royalties and favorable manufacturing costs, offset partially by expenses related to Hurricane Maria, unfavorable product mix and other inventory costs.

Cost of sales decreased to 18.1% of total revenues for 2016, driven primarily by certain manufacturing efficiencies.

Research and development

The Company groups all of its R&D activities and related expenditures into three categories: (1) Discovery Research and Translational Sciences (DRTS), (2) later-stage clinical programs and (3) marketed products. These categories include the Company’s R&D activities as set forth in the following table:

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

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

	Years ended December 31,		
	2017	2016	2015
DRTS	$972	$1,039	$997
Later-stage clinical programs	879	1,054	1,876
Marketed products	1,711	1,747	1,197
Total R&D expense	$3,562	$3,840	$4,070

The decrease in R&D expenses for 2017 was driven by decreased costs associated with later-stage clinical program support, lower external business development expense in DRTS and lower marketed-product support. All categories of R&D spend benefited from savings from transformation and process improvement efforts and we continue to advance our pipeline.

The decrease in R&D expenses for 2016 was driven primarily by decreased costs associated with later-stage clinical programs support of $822 million, offset partially by increased costs associated with marketed-products support of $550 million. All categories of R&D spend benefited from savings from transformation and process improvement efforts. The decrease was offset partially by reinvestment for the long-term benefit of the company, including an increase in DRTS for up-front milestone payments related to several collaboration transactions. Prior to approval, costs related to our launch products were categorized largely as later-stage clinical programs.

Selling, general and administrative

The decrease in Selling, general and administrative (SG&A) expense for 2017 was driven primarily by the expiration of the ENBREL residual royalty payments on October 31, 2016, offset partially by investments in product launch and marketed product support.

The increase in SG&A expense for 2016 was driven primarily by further investments in product launches, offset partially by the expiration of the ENBREL residual royalty payments on October 31, 2016.

The ENBREL co-promotion term expired in October 2013, and we were required to pay Pfizer residual royalties on a declining percentage of net ENBREL sales in the United States and Canada. Effective November 2016, there were no further residual royalty payments. The residual royalty percentage ranged from 10% to 11% in 2016 and 2015.

Other

Other operating expenses for 2017 included $284 million of net charges associated with the discontinuance of the internal development of AMG 899 and $83 million of certain net charges related to our restructuring plan. See Part IV—Note 3, Business combinations, to the Consolidated Financial Statements.

Other operating expenses for 2016 included $105 million of charges related to legal proceedings.

Other operating expenses for 2015 included $91 million of charges related to legal proceedings; certain charges related to our restructuring initiatives, including separation costs of $49 million; $31 million of write-offs of non-key assets acquired in a prior-year business combination; and $111 million of gains from the sale of assets related to our site closures.

Non-operating expenses, income and provision for income taxes

Non-operating expenses, income and provision for income taxes were as follows (dollar amounts in millions):

	Years ended December 31,		
	2017	2016	2015
Interest expense, net	$1,304	$1,260	$1,095
Interest and other income, net	$928	$629	$603
Provision for income taxes	$7,618	$1,441	$1,039
Effective tax rate	79.4 %	15.7 %	13.0 %

Interest expense, net

The increases in interest expense, net in 2017 and 2016 were due primarily to a higher average amount of debt outstanding compared with the respective prior year.

Interest and other income, net

The increase in interest and other income, net for 2017 compared with 2016 was due primarily to higher interest income that resulted from higher average investment balances and higher gains on strategic investments.

The increase in interest and other income, net for 2016 compared with 2015 was due primarily to higher interest income as a result of higher average investment balances in 2016, offset partially by higher gains on strategic equity investments in 2015.

Income taxes

The increase in our effective tax rate for 2017 compared with 2016 was due primarily to impacts of the 2017 Tax Act, including the repatriation tax on accumulated foreign earnings, offset partially by the remeasurement of certain net deferred and other tax liabilities.

The increase in our effective tax rate for 2016 compared with 2015 was due primarily to the unfavorable tax impact of changes in jurisdictional mix of income and expenses, offset partially by the adoption of a new accounting standard that amends certain aspects of the accounting for employee share-based compensation payments. One aspect of the standard requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized as an income tax benefit and expense in the income statement.

On December 22, 2017, the United States enacted the 2017 Tax Act that imposes a repatriation tax on accumulated earnings of foreign subsidiaries, implements a territorial tax system together with a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (SAB 118) that allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We currently are analyzing the 2017 Tax Act, and in certain areas, have made reasonable estimates of the effects on our consolidated financial statements and tax disclosures, including the amount of the repatriation tax and changes to our existing deferred tax balances.

The repatriation tax is based primarily on our accumulated foreign earnings and profits that we previously deferred from U.S. income taxes. We recorded an estimated amount for our repatriation tax liability of $7.3 billion as of December 31, 2017. We no longer reinvest our undistributed earnings of our foreign operations indefinitely outside the United States. In addition, we remeasured certain net deferred and other tax liabilities based on the tax rates at which they are expected to reverse in the future. The estimated amount recorded related to the remeasurement of these balances was a net benefit of $1.2 billion. The net estimated impact of the 2017 Tax Act is $6.1 billion.

We consider the key estimates on the repatriation tax, net deferred tax remeasurement and the impact on our unrealized tax benefits to be incomplete due to our continuing analysis of final year-end data and tax positions. Our analysis could affect the measurement of these balances and give rise to new deferred tax assets and liabilities. Since the 2017 Tax Act was passed late in the fourth quarter of 2017, and further guidance and accounting interpretation is expected over the next 12 months, our review is still pending. We expect to complete our analysis within the measurement period.

As previously disclosed, we received a RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. On November 29, 2017, we received a modified RAR that revised their calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution through the IRS administrative appeals process, which we believe will likely not be concluded within the next 12 months. Final resolution of the IRS audit could have a material impact on our results of consolidated operations and cash flows if not resolved favorably, however, we believe our income tax reserves are appropriately provided for all open tax years.

See Summary of Critical Accounting Policies—Income taxes, and Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

Financial Condition, Liquidity and Capital Resources

Selected financial data was as follows (in millions):

	December 31,	
	2017	2016
Cash, cash equivalents and marketable securities	$41,678	$38,085
Total assets	$79,954	$77,626
Short-term borrowings and current portion of long-term debt	$1,152	$4,403
Long-term debt	$34,190	$30,193
Stockholders' equity	$25,241	$29,875

Cash, cash equivalents and marketable securities

We now have global access to our $41.7 billion balance of cash, cash equivalents and marketable securities, as we no longer reinvest our undistributed foreign earnings indefinitely outside the United States. Under the 2017 Tax Act, we owe a repatriation tax on undistributed earnings generated from operations in foreign tax jurisdictions estimated at $7.3 billion that will be paid over eight years. See Contractual Obligations below. We will also have access to global cash generated from operations in the future.

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

Capital allocation

Consistent with the objective to optimize our capital structure, we will seek to deploy our accumulated cash balances in an efficient manner and will consider several alternatives such as share repurchases, payment of cash dividends, repayment of debt, and strategic transactions that expand our portfolio of products in areas of therapeutic interest.

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

The Board of Directors declared quarterly cash dividends of $0.79 per share of common stock in 2015, increased our quarterly cash dividend by 27% to $1.00 per share of common stock in 2016, and increased our quarterly cash dividend by 15% to $1.15 per share of common stock in 2017. In December 2017, the Board of Directors declared a cash dividend of $1.32 per share of common stock for the first quarter of 2018, an increase of 15% for this period, to be paid in March 2018.

We have also returned capital to stockholders through our stock repurchase program. During 2017, we repurchased $3.1 billion of common stock and had cash settlements of $3.2 billion. In 2016 and 2015, we repurchased $3.0 billion and $1.9 billion of our common stock, respectively. As of December 31, 2017, $4.4 billion remained available under the stock repurchase program.

In January 2018, our Board of Directors authorized an additional $10.0 billion under our stock repurchase program. Based on our confidence in the long-term outlook for our business, enhanced by the 2017 Tax Act, and consistent with our ongoing objective to return capital to our stockholders, on February 5, 2018, we announced a tender offer to purchase up to $10.0 billion of our common stock at a price not greater than $200 per share nor less than $175 per share. The tender offer expires at 12:00 Midnight, New York City time, at the end of Monday, March 5, 2018, unless the offer is extended.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt

markets and equity markets. See Part I, Item 1A. Risk Factors—Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Financing arrangements

The current and noncurrent portions of our long-term borrowings as of December 31, 2017, were $1.2 billion and $34.2 billion, respectively. The current and noncurrent portions of our long-term borrowings as of December 31, 2016, were $4.4 billion and $30.2 billion, respectively. As of December 31, 2017, Standard & Poor's Financial Services LLC (S&P), Moody's Investors Service, Inc. (Moody's) and Fitch Ratings Inc. (Fitch) assigned credit ratings to our outstanding senior notes of A with a stable outlook, Baa1 with a stable outlook and BBB with a stable outlook, respectively, which are considered investment grade. Unfavorable changes to these ratings may have an adverse impact on future financings.

During 2017, 2016 and 2015, we issued debt with aggregate principal amounts of $4.5 billion, $7.3 billion and $3.5 billion, respectively. During 2017, 2016 and 2015, we repaid debt of $4.4 billion, $3.7 billion and $2.4 billion, respectively.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating London Interbank Offered Rates (LIBOR)-based coupon over the life of the respective note. These interest rate swap contracts qualified and are designated as fair value hedges. As of December 31, 2017 and 2016, we had interest rate swap contracts with aggregate notional amounts of $9.45 billion and $6.65 billion, respectively.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts, which effectively convert the interest payments and principal repayment of the respective notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts qualified and are designated as cash flow hedges. As of December 31, 2017 and 2016, we had cross-currency swap contracts with aggregate notional amounts of $5.6 billion.

As of December 31, 2017, we had a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. During 2017, we issued and repaid an aggregate of $12.3 billion commercial paper and had a maximum outstanding balance of $1.5 billion under our commercial paper program. During 2016 and 2015, we did not issue any commercial paper. No commercial paper was outstanding as of December 31, 2017 or 2016.

In 2014, we entered into a $2.5 billion syndicated, unsecured, revolving credit agreement which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $500 million with the agreement of the banks. Each bank which is a party to the agreement has an initial commitment term of five years. We extended this term by one year during 2016 and may extend the term for an additional year with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest at LIBOR plus 1% for any amounts borrowed under this facility. As of December 31, 2017 and 2016, no amounts were outstanding under this facility.

In 2017, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2020.

Certain of our financing arrangements contain non-financial covenants. In addition, our revolving credit agreement includes a financial covenant with respect to the level of our borrowings in relation to our equity, as defined. We were in compliance with all applicable covenants under this arrangement as of December 31, 2017.

See Part IV—Note 14, Financing arrangements, and Note 17, Derivative instruments, to the Consolidated Financial Statements.

Cash flows

A summary of our cash flow activity was as follows (in millions):

	Years ended December 31,		
	2017	2016	2015
Net cash provided by operating activities	$11,177	$10,354	$9,731
Net cash used in investing activities	$(4,024)	$(8,658)	$(5,547)
Net cash used in financing activities	$(6,594)	$(2,599)	$(3,771)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities increased during 2017 due primarily to a higher operating margin and the timing of payments to vendors and receipts from customers, offset partially by higher payments to taxing authorities. Cash provided by operating activities increased during 2016 due primarily to an improved operating margin and the timing of customer payments, offset partially by inventory build, the monetization of foreign currency forward contracts in 2015 and the timing of tax payments.

Investing

Cash used in investing activities during 2017, 2016 and 2015 was due primarily to net cash outflows related to marketable securities of $3.2 billion, $7.7 billion and $4.4 billion, respectively. Capital expenditures, which were associated primarily with site development costs, including our Thousand Oaks campus, as well as manufacturing capacity expansions in Puerto Rico, Singapore and Ireland, were $664 million, $738 million and $594 million in 2017, 2016 and 2015, respectively. We currently estimate 2018 spending on capital projects to be approximately $750 million.

Financing

Cash used in financing activities during 2017 was due primarily to the repayment of debt of $4.4 billion, the payment of dividends of $3.4 billion, repurchases of our common stock of $3.2 billion and withholding taxes arising from shares withheld for share-based payments of $191 million, offset partially by net proceeds from the issuance of debt of $4.5 billion. Cash used in financing activities during 2016 was due primarily to the repayment of debt of $3.7 billion, the payment of dividends of $3.0 billion, repurchases of our common stock of $3.0 billion and withholding taxes arising from shares withheld for share-based payments of $260 million, offset partially by net proceeds from the issuance of debt of $7.3 billion. Cash used in financing activities during 2015 was due primarily to the repayment of debt of $2.4 billion, the payment of dividends of $2.4 billion, repurchases of our common stock of $1.9 billion, withholding taxes arising from shares withheld for share-based payments of $401 million and the settlement of contingent consideration obligations incurred in connection with the acquisition of a business of $253 million, offset partially by net proceeds from the issuance of debt of $3.5 billion.

See Part IV—Note 14, Financing arrangements, and Note 15, Stockholders’ equity, to the Consolidated Financial Statements.

Off-Balance Sheet Arrangements

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

Contractual Obligations

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

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

	Payments due by period as of December 31, 2017				
Contractual obligations	Total	Year 1	Years 2 and 3	Years 4 and 5	Years 6 and beyond
Long-term debt obligations [1] [2] [3] [4]	$56,763	$2,530	$9,964	$9,705	$ 34,564
Operating lease obligations [5]	650	158	242	159	91
Purchase obligations [6]	1,343	605	346	150	242
U.S. repatriation tax [7]	7,316	585	1,170	1,170	4,391
Unrecognized tax benefits (UTBs) [8]	—	—	—	—	—
Total contractual obligations	$66,072	$3,878	$11,722	$11,184	$ 39,288

(1) Long-term debt obligations include future interest payments on our fixed-rate obligations at the contractual coupon rates. To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the life of the respective note. We used an interest rate forward curve as of December 31, 2017, in computing net amounts to be paid or received under our interest rate swap contracts which resulted in an aggregate net increase in future interest payments of $22 million. See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements.

(2) Long-term debt obligations include future interest payments on our LIBOR-based variable-rate obligations. We used an interest rate forward curve as of December 31, 2017, in computing the LIBOR-based portion of interest payments on these debt obligations. See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements.

(3) Long-term debt obligations include contractual interest payments and principal repayment of our foreign-denominated debt obligations. In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our euro, pound sterling and Swiss franc denominated long-term debt, we entered into cross-currency swap contracts that effectively convert interest payments and principal repayment on this debt from euros, pounds sterling and Swiss francs to U.S. dollars. For purposes of this table, we used the contracted exchange rates in the cross-currency swap contracts to compute the net amounts of future interest payments and principal repayments on this debt. See Part IV—Note 17, Derivative instruments, to the Consolidated Financial Statements.

(4) Interest payments and the repayment of principal on our 4.375% 2018 euro Notes were translated into U.S. dollars at the foreign currency exchange rate in effect as of December 31, 2017. See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements.

(5) Operating lease obligations exclude $205 million of future receipts under noncancelable subleases of abandoned facilities.

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

(7) Under the 2017 Tax Act, we will elect to pay the repatriation tax primarily related to our prior indefinitely invested earnings of our foreign operations in eight annual installments beginning April 2018. See Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

(8) Liabilities for UTBs (net of foreign tax credits and federal tax benefit of state taxes) and related accrued interest and penalties of $2.4 billion as of December 31, 2017, are not included in the table above because, due to their nature, there is a high degree of uncertainty regarding the timing of future cash outflows and other events that extinguish these liabilities.

In addition to amounts in the table above, we are contractually obligated to pay additional amounts, which in the aggregate are significant, upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties, including contingent consideration incurred in the acquisition of BioVex Group Inc. (BioVex). These payments are contingent upon the occurrence of various future events,

substantially all of which have a high degree of uncertainty of occurring. These contingent payments have not been included in the table above, and, except with respect to the fair value of the contingent consideration obligations, are not recorded on our Consolidated Balance Sheets. As of December 31, 2017, the maximum amount that may be payable in the future for agreements we have entered into with third parties is $7.0 billion, including $325 million of contingent consideration payments in connection with the acquisition of BioVex. Contingent consideration with respect to the acquisition of Dezima Pharma B.V. was excluded due to the discontinuation of the development of AMG 899, upon which payments are based. See Part IV—Note 16, Fair value measurement, to the Consolidated Financial Statements.

Summary of Critical Accounting Policies

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

Product sales and sales deductions

Revenues from sales of our products are recognized when the products are shipped and title and risk of loss have passed. Product sales are recorded net of accruals for estimated rebates, wholesaler chargebacks, cash discounts and other deductions (collectively, sales deductions) and returns, which are established at the time of sale.

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

	Rebates	Chargebacks	Other deductions	Total
Balance as of December 31, 2014	$1,120	$ 196	$ 63	$1,379
Amounts charged against product sales	2,734	4,275	732	7,741
Payments	(2,735)	(4,198)	(701)	(7,634)
Balance as of December 31, 2015	1,119	273	94	1,486
Amounts charged against product sales	3,479	5,270	905	9,654
Payments	(3,181)	(5,201)	(884)	(9,266)
Balance as of December 31, 2016	1,417	342	115	1,874
Amounts charged against product sales	4,909	6,098	992	11,999
Payments	(4,459)	(6,168)	(999)	(11,626)
Balance as of December 31, 2017	$1,867	$ 272	$ 108	$2,247

For the years ended December 31, 2017, 2016 and 2015, total sales deductions were 35%, 31% and 27% of gross product sales, respectively. Included in the amounts are immaterial net adjustments related to prior-year sales due to changes in estimates. Such amounts represent less than 1% of the aggregate sales deductions charged against product sales in each of the three years ended December 31, 2017.

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

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

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

Wholesaler chargebacks relate to our contractual agreements to sell products to healthcare providers in the United States at fixed prices that are lower than the prices we charge wholesalers. When healthcare providers purchase our products through wholesalers at these reduced prices, wholesalers charge us for the difference between their purchase price and the contractual price

between Amgen and the healthcare providers. The provision for chargebacks is based on the expected sales by our wholesaler customers to healthcare providers. Accruals for wholesaler chargebacks are less difficult to estimate than rebates and closely approximate actual results since chargeback amounts are fixed at the date of purchase by the healthcare providers, and we generally settle the liability for these deductions within a few weeks.

Product returns

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

Income taxes

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

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

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

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

On December 22, 2017, the SEC staff issued SAB 118 to address the accounting implications of the 2017 Tax Act. The effects of the 2017 Tax Act are recognized upon enactment, however, SAB 118 permits a company to recognize provisional amounts when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law. The measurement period to finalize our calculations cannot extend beyond one year of the enactment date. Key provisions that have a significant impact on our consolidated financial statements and where we have recognized estimated amounts include the recognition of liabilities for taxes on repatriation of accumulated foreign earnings and the remeasurement of certain net deferred and other tax liabilities.

Furthermore, the 2017 Tax Act permits a company, upon election, to pay the repatriation tax over eight years on an interest-free basis, which we expect to do. In January 2018, the Financial Accounting Standards Board staff issued Staff Q&A, Topic 740, No. 2, Whether to Discount the Tax Liability on Deemed Repatriation, which notes that the repatriation tax liability should not be discounted. See Part IV—Note 5, Income taxes, to the Consolidated Financial Statements.

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

Contingencies

In the ordinary course of business, we are involved in various legal proceedings and other matters such as intellectual property disputes, contractual disputes, governmental investigations and class action suits which are complex in nature and have outcomes that are difficult to predict. Certain of these proceedings are discussed in Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We consider all relevant factors when making assessments regarding these contingencies.

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

Valuation of assets and liabilities in connection with business combinations

We have acquired and continue to acquire intangible assets in connection with business combinations. These intangible assets consist primarily of technology associated with currently marketed human therapeutic products and IPR&D product candidates. Discounted cash flow models are typically used to determine the fair values of these intangible assets for purposes of allocating consideration paid to the net assets acquired in a business combination. See Part IV—Note 3, Business combinations, to the Consolidated Financial Statements. These models require the use of significant estimates and assumptions, including, but not limited to:

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

Significant estimates and assumptions are also required to determine the acquisition date fair values of any contingent consideration obligations incurred in connection with business combinations. In addition, we must revalue these obligations each subsequent reporting period until the related contingencies are resolved and record changes in their fair values in earnings. The acquisition date fair values of contingent consideration obligations incurred or assumed in the acquisitions of businesses were determined using a combination of valuation techniques. Significant estimates and assumptions required for these valuations included, but were not limited to, the probability of achieving regulatory milestones, product sales projections under various scenarios and discount rates used to calculate the present value of the required payments. These estimates and assumptions are required to be updated in order to revalue these contingent consideration obligations each reporting period. Accordingly, subsequent changes in underlying facts and circumstances could result in changes in these estimates and assumptions, which could have a material impact on the estimated future fair values of these obligations. For example, during 2017, we discontinued the internal development of AMG 899 and consequently reduced the related contingent consideration liabilities. See Part IV—Note 16, Fair value measurement, to the Consolidated Financial Statements.

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

Impairment of long-lived assets

We review the carrying value of our property, plant and equipment and our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows to be generated by the long-lived asset is compared to the carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset’s fair value and its carrying value. Indefinite-lived intangible assets, composed of IPR&D projects acquired in a business combination which have not reached technological feasibility or lack regulatory approval at the time of acquisition, are reviewed for impairment

annually, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon establishment of technological feasibility or regulatory approval. We determine impairment by comparing the fair value of the asset to its carrying value. If the

asset's carrying value exceeds its fair value, an impairment charge is recorded for the difference and its carrying value is reduced accordingly.

Estimating future cash flows of an IPR&D product candidate for purposes of an impairment analysis requires us to make significant estimates and assumptions regarding the amount and timing of costs to complete the project and the amount, timing and probability of achieving revenues from the completed product similar to how the acquisition date fair value of the project was determined, as described above. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market these products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods which could have a material adverse effect on our results of operations. For example, during 2017, we discontinued the internal development of AMG 899 and consequently recorded an IPR&D asset impairment charge. See Part IV—Note 12, Goodwill and other intangible assets, to the Consolidated Financial Statements.

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

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

In the discussion that follows, we have assumed a hypothetical change in interest rates of 100 basis points from those as of December 31, 2017 and 2016. We have also assumed a hypothetical 20% change in foreign currency exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2017 and 2016.

Interest rate sensitive financial instruments

Our portfolio of available-for-sale interest-bearing securities as of December 31, 2017 and 2016, was composed of: U.S. Treasury securities and other government-related debt securities; corporate debt securities; residential mortgage-backed and other mortgage- and asset-backed securities; money market mutual funds; and other short-term interest-bearing securities, composed principally of commercial paper. The fair values of our investment portfolio of interest-bearing securities were $41.2 billion and $37.6 billion as of December 31, 2017 and 2016, respectively. Duration is a sensitivity measure that can be used to approximate the change in the value of a security that will result from a 100 basis point change in interest rates. Applying a duration model, a hypothetical 100 basis point increase in interest rates as of December 31, 2017 and 2016, would have resulted in a reduction in the fair values of these securities of $1.1 billion and $900 million, respectively, on these dates. In addition, a hypothetical 100 basis point decrease in interest rates as of December 31, 2017 and 2016, would not result in a material effect on income in the respective ensuing year.

As of December 31, 2017, we had outstanding debt with a carrying value of $35.3 billion and a fair value of $38.6 billion. As of December 31, 2016, we had outstanding debt with a carrying value of $34.6 billion and a fair value of $36.5 billion. Our outstanding debt was composed primarily of debt with fixed interest rates with variable rate debt having a carrying value of $850 million and $1.5 billion as of December 31, 2017 and 2016, respectively. Changes in interest rates do not affect interest expense on fixed-rate debt. Changes in interest rates would, however, affect the fair values of fixed-rate debt. A hypothetical 100 basis point decrease in interest rates relative to interest rates as of December 31, 2017 and 2016, would have resulted in an increase of $3.3 billion and $3.0 billion, respectively, in the aggregate fair value of our outstanding debt on each of these dates. The analysis for the debt does not consider the impact that hypothetical changes in interest rates would have on the related interest rate swap contracts and cross-currency swap contracts, discussed below.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts which qualified and were designated for accounting purposes as fair value hedges, for certain of our fixed-rate debt. These interest rate swap contracts effectively converted a fixed-rate interest coupon to a floating-rate LIBOR-based coupon

over the life of the respective note. Interest rate swap contracts with aggregate notional amounts of $9.45 billion and $6.65 billion were outstanding as of December 31, 2017 and 2016, respectively. A hypothetical 100 basis point increase in interest rates relative to interest rates as of December 31, 2017 and 2016, would have resulted in reductions in fair values of $420 million and $240 million, respectively, on our interest rate swap contracts on these dates and would not result in a material effect on the related income in the respective ensuing years. The analysis for the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair values of debt that these interest rate sensitive instruments were designed to offset.

As of December 31, 2017 and 2016, we had outstanding cross-currency swap contracts with aggregate notional amounts of $5.6 billion that hedge certain of our foreign-currency denominated debt and related interest payments. These contracts effectively convert interest payments and principal repayment of this debt to U.S. dollars from euros, pounds sterling and Swiss francs and are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates as of December 31, 2017 and 2016, would have resulted in reductions in the fair values of our cross-currency swap contracts of $390 million and $450 million, respectively.

Foreign currency sensitive financial instruments

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

As of December 31, 2017, we had outstanding euro, pound sterling and Swiss franc denominated debt with a principal carrying value and fair value of $6.2 billion and $6.7 billion, respectively. As of December 31, 2016, we had outstanding euro, pound sterling and Swiss franc denominated debt with a principal carrying value and fair value of $5.5 billion and $6.0 billion, respectively. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2017, would have resulted in an increase in fair value of this debt of $1.3 billion on this date and a reduction in income in the ensuing year of $1.2 billion. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2016, would have resulted in an increase in fair value of this debt of $1.2 billion on this date and a reduction in income in the ensuing year of $1.1 billion. The impact on income from these hypothetical changes in foreign currency exchange rates would be substantially offset by the impact such changes would have on related cross-currency swap contracts, which are in place for the majority of the foreign currency denominated debt.

We have cross-currency swap contracts that are designated as cash flow hedges of certain of our debt denominated in euros, pounds sterling and Swiss francs with an aggregate notional amount of $5.6 billion, as of December 31, 2017 and 2016. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates, would have resulted in a reduction in the fair values of these contracts of $1.3 billion and $1.2 billion on these dates, respectively. The impact on income in the ensuing years from these contracts of this hypothetical adverse movement in foreign currency exchange rates would be fully offset by the corresponding hypothetical changes in the carrying amounts of the related hedged debt.

We enter into foreign currency forward and options contracts that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2017, we had open foreign currency forward and options contracts, primarily euro-based, with notional amounts of $4.6 billion and $74 million, respectively. As of December 31, 2016, we had open foreign currency forward and options contracts, primarily euro-based, with notional amounts of $3.4 billion and $608 million, respectively. As of December 31, 2017 and 2016, the fair values of these contracts were a $200 million liability and a $200 million asset, respectively. With regard to foreign currency forward and option contracts that were open as of December 31, 2017, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2017, would have resulted in a reduction in fair value of these contracts of $930 million on this date and, in the ensuing year, a reduction in income of $360 million. With regard to contracts that were open as of December 31, 2016, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2016, would have resulted in a reduction in fair value of these contracts of $650 million on this date and, in the ensuing year, a reduction in income of $300 million. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign currency sensitive instruments were designed to offset.

As of December 31, 2017 and 2016, we had open foreign currency forward contracts with notional amounts of $757 million and $666 million, respectively, that hedged fluctuations of certain assets and liabilities denominated in foreign currencies but were not designated as hedges for accounting purposes. These contracts had no material net unrealized gains or losses as of December 31, 2017 and 2016. With regard to these foreign currency forward contracts that were open as of December 31, 2017 and 2016, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would not have a material effect on the fair values of these contracts or related income in the respective ensuing years. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on assets and liabilities that these foreign currency sensitive instruments were designed to offset.

Market price sensitive financial instruments

As of December 31, 2017 and 2016, we were also exposed to price risk on equity securities included in our portfolio of investments, which were acquired primarily for the promotion of business and strategic objectives. These investments are generally in small capitalization stocks in the biotechnology industry sector. Price risk relative to our equity investment portfolio as of December 31, 2017 and 2016, was not material.

Counterparty credit risks

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

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

Item 9A. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance Amgen's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2017.

Management determined that, as of December 31, 2017, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

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

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2017. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our assessment, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

The effectiveness of the Company’s internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing below, which expresses an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting as of December 31, 2017.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Amgen Inc.

Opinion on Internal Control over Financial Reporting

We have audited Amgen Inc.'s internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Amgen Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Amgen Inc. as of December 31, 2017 and 2016, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 of the Company and our report dated February 13, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Los Angeles, California

February 13, 2018

Item 9B. OTHER INFORMATION

Not applicable.

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about our Directors is incorporated by reference from the section entitled ITEM 1—ELECTION OF DIRECTORS in our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2017 (the Proxy Statement). Information about compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated by reference from the section entitled OTHER MATTERS—Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement. Information about the procedures by which stockholders may recommend nominees for the Board of Directors is incorporated by reference from APPENDIX A—AMGEN INC. BOARD OF DIRECTORS GUIDELINES FOR DIRECTOR QUALIFICATIONS AND EVALUATIONS and OTHER MATTERS—Stockholder Proposals for the 2019 Annual Meeting in our Proxy Statement. Information about our Audit Committee, members of the committee and our Audit Committee financial experts is incorporated by reference from the section entitled CORPORATE GOVERNANCE—Audit Committee in our Proxy Statement. Information about our executive officers is contained in the discussion entitled Item 1. Business—Executive Officers of the Registrant.

Code of Ethics

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

Item 11. EXECUTIVE COMPENSATION

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

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

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table sets forth certain information as of December 31, 2017, concerning the shares of our common stock that may be issued under any form of award granted under our equity compensation plans in effect as of December 31, 2017 (including upon the exercise of options, the vesting of awards of restricted stock units (RSUs), or when performance units are earned, and related dividend equivalents have been granted).

	(a)	(b)	(c)
Plan category	Number of securities to be issued upon exercise of outstanding options and rights	Weighted average exercise price outstanding options and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by Amgen security holders:			
Amended and Restated 2009 Equity Incentive Plan[1]	9,842,199	$ 127.10	36,100,581
Amended and Restated 1991 Equity Incentive Plan[2]	23,845	—	—
Amended and Restated Employee Stock Purchase Plan	—	—	4,761,810
Total approved plans	9,866,044	$ 127.10	40,862,391
Equity compensation plan not approved by Amgen security holders:			
Amgen Profit Sharing Plan for Employees in Ireland[3]	—	—	107,908
Total unapproved plans	—	$ —	107,908
Total all plans	9,866,044	$ 127.10	40,970,299

(1) The Amended and Restated 2009 Equity Incentive Plan employs a fungible share counting formula for determining the number of shares available for issuance under the plan. In accordance with this formula, each option or stock appreciation right counts as one share, while each restricted stock unit, performance unit or dividend equivalent counts as 1.9 shares. The number under column (a) represents the actual number of shares issuable under our outstanding awards without giving effect to the fungible share counting formula. The number under column (c) represents the number of shares available for issuance under this plan based on each such available share counting as one share. Commencing with the grants made in April 2012, RSUs and performance units accrue dividend equivalents that are payable in shares only to the extent and when the underlying RSUs vest or underlying performance units have been earned and the related shares are issued to the grantee. The performance units granted under this plan are earned based on the accomplishment of specified performance goals at the end of their respective three-year performance periods; the number of performance units granted represent target performance and the maximum number of units that could be earned based on our performance is 150% of the performance units granted in 2015 and 200% of performance units granted in 2016 and 2017.

As of December 31, 2017, the number of outstanding awards under column (a) includes: (i) 3,963,390 shares issuable upon the exercise of outstanding options with a weighted-average exercise price of $127.10; (ii) 3,664,499 shares issuable upon the vesting of outstanding RSUs (including 177,631 related dividend equivalents); and (iii) 2,214,310 shares subject to outstanding 2015, 2016 and 2017 performance units (including 99,373 related dividend equivalents). The weighted-average exercise price shown in column (b) is for the outstanding options only. The number of available

shares under column (c) represents the number of shares that remain available for future issuance under this plan as of December 31, 2017, employing the fungible share formula and presumes the issuance of target shares under the performance units granted in 2015, 2016 and 2017 and related dividend equivalents. The numbers under columns (a) and (c) do not give effect to the additional shares that could be issuable in the event above target on the performance goals under these outstanding performance units are achieved. Maximum performance under these goals could result in 150% of target shares being awarded for performance units granted in 2015 and 200% of target shares being awarded for performance units granted in 2016 and 2017.

(2) This plan has terminated as to future grants. The number under column (a) with respect to this plan includes 23,845 shares issuable upon the settlement of deferred RSUs (including 3,053 related dividend equivalents).

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

Security Ownership of Directors and Executive Officers and Certain Beneficial Owners

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

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

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

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)1. Index to Financial Statements

The following Consolidated Financial Statements are included herein:

(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
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 13, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)

4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.6	Officer's Certificate of Amgen Inc., dated January 1, 1992, as supplemented by the First Supplemental Indenture, dated February 26, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)

4.7	Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.8	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.9	Officers' Certificate of Amgen Inc., dated May 30, 2007, including forms of the Company's Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
4.10	Officers' Certificate of Amgen Inc., dated May 23, 2008, including forms of the Company's 6.15% Senior Notes due 2018 and 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)
4.11	Officers' Certificate of Amgen Inc., dated January 16, 2009, including forms of the Company's 5.70% Senior Notes due 2019 and 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)
4.12	Officers' Certificate of Amgen Inc., dated March 12, 2010, including forms of the Company's 4.50% Senior Notes due 2020 and 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.)
4.13	Officers' Certificate of Amgen Inc., dated September 16, 2010, including forms of the Company's 3.45% Senior Notes due 2020 and 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)
4.14	Officers' Certificate of Amgen Inc., dated June 30, 2011, including forms of the Company's 2.30% Senior Notes due 2016, 4.10% Senior Notes due 2021 and 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)
4.15	Officers' Certificate of Amgen Inc., dated November 10, 2011, including forms of the Company's 1.875% Senior Notes due 2014, 2.50% Senior Notes due 2016, 3.875% Senior Notes due 2021 and 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)
4.16	Officers' Certificate of Amgen Inc., dated December 5, 2011, including forms of the Company's 4.375% Senior Notes due 2018 and 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)
4.17	Officers' Certificate of Amgen Inc., dated May 15, 2012, including forms of the Company's 2.125% Senior Notes due 2017, 3.625% Senior Notes due 2022 and 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)
4.18	Officers' Certificate of Amgen Inc., dated September 13, 2012, including forms of the Company's 2.125% Senior Notes due 2019 and 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)
4.19	Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)

4.20	Officers' Certificate of Amgen Inc., dated May 22, 2014, including forms of the Company's Senior Floating Rate Notes due 2017, Senior Floating Rate Notes due 2019, 1.250% Senior Notes due 2017, 2.200% Senior Notes due 2019 and 3.625% Senior Notes due 2024. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
4.21	Officer's Certificate of Amgen Inc., dated May 1, 2015, including forms of the Company's 2.125% Senior Notes due 2020, 2.700% Senior Notes due 2022, 3.125% Senior Notes due 2025 and 4.400% Senior Notes due 2045. (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.)
4.22	Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including forms of the Company's 1.250% Senior Notes due 2022 and 2.000% Senior Notes due 2026. (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.)
4.23	Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.24	Terms of the Bonds for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)

4.25	Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.26	Registration Rights Agreement, dated as of June 14, 2016, by and among Amgen Inc., Credit Suisse Securities (USA) LLC, J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Mizuho Securities USA Inc., as lead dealer managers, and Drexel Hamilton, LLC and The Williams Capital Group, L.P., as co-dealer managers. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 1.850% Senior Notes due 2021, 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.28	Officer's Certificate of Amgen Inc., dated as of May 11, 2017, including in forms of the Company's Senior Floating Rate Notes due 2019, Senior Floating Rate Notes due 2020, 1.900% Senior Notes due 2019, 2.200% Senior Notes due 2020 and 2.650% Senior Notes due 2022. (Filed as an exhibit to Form 8-K on May 11, 2017 and incorporated by reference.)
4.29	Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated by reference.)
10.1+	Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
10.2+	First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.)
10.3+	Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)
10.4+*	Form of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 12, 2017.)
10.5+*	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 12, 2017.)
10.6+*	Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.)
10.7+*	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.)
10.8+*	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on October 24, 2017.)
10.9+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)

10.10+*	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on October 24, 2017.)
10.11+*	Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program.
10.12+	Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.13+	First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.14+	Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.)

10.15+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.16+	First Amendment to the Amgen Inc. Executive Incentive Plan, effective December 13, 2012. (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.)
10.17+	Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.18+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.19+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.20+	Agreement between Amgen Inc. and David W. Meline, effective July 21, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2014 on October 29, 2014 and incorporated herein by reference.)