AMGEN INC
Form 10-K
February 16, 2016

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, 2015
OR

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

Commission file number 000-12477
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 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. (Check one):

Large accelerated filer x	Accelerated filer ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 $102,117,764,803 as of June 30, 2015(A)

(A) Excludes 93,926,800 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, 2015. 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.

752,091,038

(Number of shares of common stock outstanding as of February 9, 2016)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2016 Annual Meeting of stockholders to be held May 19, 2016, 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 biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen was incorporated in California in 1980 and became a Delaware corporation in 1987. Amgen operates in one business segment: human therapeutics.

Significant Developments

Following is a summary of significant developments affecting our business that have occurred since the filing of our Annual Report on Form 10-K for the year ended December 31, 2014, and in early 2016.

Products/Pipeline

Cardiovascular

Corlanor® (ivabradine)

- In April 2015, we announced that the U.S. Food and Drug Administration (FDA) granted approval of Corlanor® to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤35 percent, who are in sinus rhythm with resting heart rate ≥70 beats per minute and either are on maximally tolerated doses of beta blockers or have a contraindication to beta blocker use.

Repatha® (evolocumab)

- In July 2015, we announced that the European Commission (EC) granted marketing authorization for Repatha® for the treatment of high cholesterol, as an adjunct to diet:
  - In combination with statins or other lipid-lowering therapies in patients unable to control their low-density lipoprotein cholesterol (LDL-C) with maximum tolerated statin doses, or
  - Alone or in combination with other lipid-lowering therapies in patients who are statin intolerant or for whom a statin is contraindicated.

  Repatha® is also approved in the European Union (EU) in combination with other lipid-lowering agents in patients with homozygous familial hypercholesterolemia (age 12 and over). The effect of Repatha® on cardiovascular morbidity and mortality has not been determined.
- In August 2015, we announced that the FDA granted approval of Repatha® as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C; and as an adjunct to diet and other LDL-lowering therapies for the treatment of patients with homozygous familial hypercholesterolemia, who require additional lowering of LDL-C. The effect of Repatha® on cardiovascular morbidity and mortality has not been determined.
- In September 2015, we announced that we submitted an application to the FDA for a single-dosing option for the monthly administration of Repatha®. The FDA has set a July 10, 2016, Prescription Drug User Fee Act (PDUFA) target action date as a goal for the completion of their review of our application.
- In January 2016, we, together with our joint venture partner Astellas Pharma, Inc., announced that the Japanese Ministry of Health, Labour and Welfare approved Repatha® for the treatment of patients with familial hypercholesterolemia or hypercholesterolemia who have high risk of cardiovascular events and do not adequately respond to HMG-CoA reductase inhibitors (statins).
- In February 2016, we announced that the phase 3 GAUSS-3 (Goal Achievement After Utilizing an Anti-PCSK9 Antibody in Statin Intolerant Subjects-3) trial evaluating Repatha® in patients with high cholesterol who cannot tolerate statins, met its co-primary endpoints.

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Inflammation

Brodalumab

- In August 2015, we terminated participation in the co-development and commercialization of brodalumab with AstraZeneca plc (AstraZeneca).

Nephrology

Aranesp® (darbepoetin alfa)

- In February 2016, we announced that the randomized, double-blind, placebo-controlled phase 3 ARCADE trial met its primary endpoint of reducing the incidence of red blood cell transfusions in anemic patients with low and intermediate-1 risk myelodysplastic syndrome (MDS).

Parsabiv™ (etelcalcetide)*

- In September 2015, we announced that we submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Parsabiv,™ an intravenous calcimimetic agent, for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.
- In November 2015, we announced that the FDA accepted for review our New Drug Application (NDA) for Parsabiv™ for the treatment of SHPT in patients with CKD on hemodialysis. The FDA has set an August 24, 2016, PDUFA target action date.

Neuroscience

AMG 334

- In July 2015, we announced that we initiated phase 3 studies in episodic migraine. AMG 334 is being jointly developed with Novartis AG (Novartis).

Oncology

BLINCYTO® (blinatumomab)

- In November 2015, we announced that the EC granted conditional marketing authorization for BLINCYTO® for the treatment of adults with Philadelphia chromosome-negative (Ph-) relapsed or refractory B-precursor acute lymphoblastic leukemia (ALL).
- In February 2016, we announced that the phase 3 TOWER study evaluating the efficacy of BLINCYTO® versus standard of care in adult patients with Ph- relapsed or refractory B-cell precursor ALL, met its primary endpoint of improved overall survival (OS) based on the results of a prespecified interim analysis.

IMLYGIC™ (talimogene laherparepvec)

- In October 2015, we announced that the FDA granted approval of IMLYGIC™ for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery. IMLYGIC™ has not been shown to improve OS or have an effect on visceral metastases.
- In December 2015, we announced that the EC approved the use of IMLYGIC™ for the treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a), with no bone, brain, lung or other visceral disease.

Kyprolis® (carfilzomib)

- In April 2015, we announced the initiation of a phase 3 study with weekly dosing in relapsed and refractory multiple myeloma.
- In July 2015, we announced that the FDA approved the supplemental NDA (sNDA) for Kyprolis® in combination with Revlimid® (lenalidomide) and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior lines of therapy, based on the phase 3 ASPIRE (CArfilzomib, Lenalidomide, and DexamethaSone versus Lenalidomide and Dexamethasone for the treatment of PatIents with Relapsed Multiple MyEloma) trial.
- In November 2015, we announced that the EC granted marketing authorization for Kyprolis® in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy, based on the phase 3 ASPIRE trial.

* FDA provisionally approved trade name

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- In December 2015, we announced that we submitted to the EMA a Variation to the MAA to expand the indication for Kyprolis® in combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy based on the data from the ENDEAVOR (RandomizEd, OpeN Label, Phase 3 Study of Carfilzomib Plus DExamethAsone Vs Bortezomib Plus DexamethasOne in Patients With Relapsed Multiple Myeloma) trial.
- In January 2016, we announced that the FDA approved the sNDA of Kyprolis® in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. The FDA also granted full approval for Kyprolis® as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy. The combination with dexamethasone was approved based on the ENDEAVOR trial.

Neulasta® (pegfilgrastim)

- In March 2015, we announced the Neulasta® Delivery kit, now known as the Neulasta® Onpro™ Kit, was available in the United States. The Neulasta® Onpro™ Kit includes a specially designed single-use prefilled syringe co-packaged with the new On-body Injector for Neulasta® that enables the healthcare provider to initiate administration of Neulasta® on the same day as chemotherapy—with delivery of the patient's full dose of Neulasta® the day following chemotherapy administration, consistent with the Neulasta® prescribing information. This eliminates the need for patients to return to their healthcare provider the day after chemotherapy, which would otherwise be needed to receive the Neulasta® injection.

Trebananib

- In April 2015, we announced that we stopped administration of blinded investigational product in the phase 3 study of trebananib in first-line ovarian cancer based on a recommendation by the Data Safety Monitoring Committee.

Vectibix® (panitumumab)

- In April 2015, we announced that the EC approved a new use of Vectibix® as first-line treatment in combination with FOLFIRI for the treatment of adult patients with wild-type RAS metastatic colorectal cancer (mCRC).
- In June 2015, we announced that the phase 3 study evaluating Vectibix® and best supportive care (BSC) compared to BSC alone in patients with chemorefractory wild-type KRAS (exon 2) mCRC, met its primary endpoint.

Bone health

Prolia® (denosumab)

- In June 2015, we announced that the phase 3 study evaluating the treatment effect of adjuvant Prolia® therapy in postmenopausal women with early hormone receptor positive breast cancer receiving aromatase inhibitor therapy, met its primary endpoint.

Romosozumab

- In September 2015, we and UCB, our collaboration partner in the development of romosozumab, announced that the open label phase 3 STRUCTURE (STudy evaluating effect of RomosozUmab Compared with Teriparatide in postmenopaUsal women with osteoporosis at high risk for fracture pReviously treated with bisphosphonatE therapy) trial met its primary endpoint.

Biosimilars

- In September 2015, we and Allergan plc (Allergan), our collaboration partner in the development and commercialization of biosimilar candidate ABP 215, announced that a phase 3 study of ABP 215 compared with Avastin® (bevacizumab) met its primary and secondary endpoints.
- In January 2016, we announced that the FDA accepted for review our Biologics License Application (BLA) for ABP 501, a biosimilar candidate to Humira® (adalimumab). The FDA has set a September 25, 2016, Biosimilar User Fee Act target action date. In addition, in December 2015, we announced that we submitted an MAA to the EMA.

Marketing, Distribution and Selected Marketed Products

The largest concentration of our sales and marketing forces are based in the United States and Europe. Additionally, we continue to expand the commercialization and marketing of our products into new geographic territories, including parts of Latin America, the Middle East and Asia. This expansion can occur either via establishing our own affiliate, acquiring existing third party businesses or product rights, or in partnering with third parties. Use of our own sales and marketing forces versus a third-party varies across these markets. This typically depends on several factors including the nature of entry into the new market, the size of opportunity and the 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 who we utilize as the principal means of distributing our products to healthcare providers. We also market certain products directly to consumers through direct-to-consumer print and television advertising, 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 accounted for more than 10% of total revenues for each of the years ended December 31, 2015, 2014 and 2013. On a combined basis, these wholesalers accounted for approximately 97%, 94% and 93% of our U.S. gross product sales, respectively, and approximately 81%, 77% and 75% of our worldwide gross revenues, respectively. We monitor the financial condition of our larger customers, and we limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit.

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 December 31, 2015, 2014 and 2013.

Enbrel® (etanercept)

We market ENBREL primarily in the United States. It was launched in 1998 and is used primarily in the 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.

Pfizer Inc. (Pfizer) has the rights to market and sell ENBREL outside the United States and Canada.

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 people with certain types of cancer (non-myeloid) who receive anti-cancer medicines (chemotherapy) that can cause fever and a low blood cell count. In March 2015, the Neulasta® Onpro™ Kit became available in the United States.

ESAs (erythropoiesis-stimulating agents)

Aranesp® (darbepoetin alfa)

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

EPOGEN® (epoetin alfa)

We market EPOGEN® in the United States for dialysis patients. It was launched in 1989, and we market it for the indication to treat a lower-than-normal number of red blood cells (anemia) caused by CKD in patients on dialysis to lessen the need for red blood cell transfusions. The majority of our sales are to two large dialysis providers. Aranesp® and EPOGEN® compete with each other in the United States, primarily in the dialysis setting.

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 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 skeletal-related events (SREs) (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumors. It is not indicated for the prevention of SREs in patients with multiple myeloma. XGEVA® was launched in Europe in 2011, and is used primarily in the indication for the prevention of SREs in adults with bone metastases from solid tumors.

Prolia® (denosumab)

We market Prolia® primarily in the United States and Europe. It 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 fractures.

NEUPOGEN® (filgrastim)

We market NEUPOGEN®, a recombinant-methionyl human granulocyte colony-stimulating factor (G-CSF), primarily in the United States, Canada and Europe. NEUPOGEN® was launched in 1991, and is used primarily in the indication to help reduce the chance of infection due to a low white blood cell count, in people with certain types of cancer (non-myeloid) who receive anti-cancer medicines (chemotherapy) that can cause fever and a low blood cell count.

Other Marketed Products

We market several other products including Vectibix® (panitumumab), Nplate® (romiplostim), Kyprolis® (carfilzomib), BLINCYTO® (blinatumomab), Repatha® (evolocumab), Corlanor® (ivabradine) and IMLYGIC™ (talimogene laherparepvec).

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 separately listed.

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
Neulasta® (pegfilgrastim)	Europe	Pegylated G-CSF(1)	2/8/2015
Aranesp® (darbepoetin alfa)	U.S.	Glycosylation analogs of erythropoietin proteins	5/15/2024
	Europe	Glycosylation analogs of erythropoietin proteins(1)	8/16/2014
Sensipar®/ Mimpara® (cinacalcet)	U.S.	Methods of treatment	12/14/2016
	U.S.	Calcium receptor-active molecules	3/8/2018
	Europe	Calcium receptor-active molecules(1)	10/23/2015
Prolia®/ XGEVA® (denosumab)	U.S.	RANKL antibodies; and methods of use(2)	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	RANKL antibodies(1)	12/22/2017
	Europe	Medical use of RANKL antibodies(1)	4/15/2018
	Europe	RANKL antibodies including epitope binding	2/23/2021
	Europe	RANKL antibodies including sequences(1)	6/25/2022
Vectibix® (panitumumab)	U.S.	Human monoclonal antibodies to epidermal growth factor receptor (EGFr)	4/8/2020
	Europe	Human monoclonal antibodies to EGFr(1)	5/5/2018
Nplate® (romiplostim)	U.S.	Thrombopoietic compounds	1/19/2022
	Europe	Thrombopoietic compounds(1)	10/22/2019
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	8/8/2025
BLINCYTO® (blinatumomab)	U.S.	Bifunctional polypeptides(3)	4/21/2019
	U.S.	Method of administration	9/28/2027
	Europe	Bifunctional polypeptides	11/26/2024
	Europe	Method of administration	11/29/2026
Repatha® (evolocumab)	U.S.	Antibodies(3)	10/25/2029
	U.S.	Methods of treatment	10/8/2030
IMLYGIC™ (talimogene laherparepvec)	U.S.	Compositions and method of treatment(3)	1/22/2021
	Europe	Composition and uses	1/22/2021

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

- pegfilgrastim - France, Germany, Italy, Spain, and the United Kingdom, expiring in August 2017

- darbepoetin alfa - France, Germany, Italy, Spain, and the United Kingdom, expiring in June 2016
- denosumab - France, Italy, Spain and the United Kingdom, expiring in 2025
- cinacalcet - France, Germany, Italy, Spain, and the United Kingdom, expiring in 2019
- panitumumab - France, Germany, Italy, Spain, and the United Kingdom, expiring in 2022
- romiplostim - France, Italy, Spain, and the United Kingdom, expiring in 2024

(2) 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.

(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. Our products compete with other products or treatments for diseases for which our products may be indicated. Our competitors market products or are actively engaged in research and development (R&D) in areas where we have products or where we are developing product candidates or new indications for existing products. Our competitive positions may be based on, among other things, safety, efficacy, reliability, availability, patient convenience/delivery devices, price, reimbursement, access and timing of market entry and patent position and expiration.

Certain of the existing patents on our principal products have recently expired and we face new and increasing competition, including from biosimilars. 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 "similar" to the original reference product. See Government Regulation. We expect the adverse impact from biosimilars to be more like branded biologics than generic small molecules. We expect patients, providers and payers to place a high value on the reputation, reliability and safety of biosimilars. Zarxio,™ a biosimilar version of NEUPOGEN® from Sandoz, a Novartis company (Sandoz), which launched in the United States on September 3, 2015, is the first biosimilar entrant into the U.S. market. Companies are developing biosimilar versions of EPOGEN® and Neulasta®, along with additional biosimilar versions of NEUPOGEN®. We expect our products to continue to generate substantial sales and cash flow for years to come even after competitors enter the market. We are prepared to compete and will leverage the experience that we have had in the United States versus branded competition as well as our considerable experience 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 a reduction of the price that 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, clinical trials may include prospective clinical trials, observational studies, registries and other studies). For further discussion, 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 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)/Merck & Company, Inc. (Merck)
	U.S. & Canada	HUMIRA®	AbbVie Inc.
	U.S. & Canada	STELARA®(2)	Janssen(1)
Neulasta®	Europe	Lonquex®	Teva Pharmaceutical Industries Ltd. (Teva)
	Europe	Filgrastim biosimilars(3)	Various
Aranesp®	U.S.	PROCRIT®(4)	Janssen(1)
	Europe	EPREX®/ERYPO®	Janssen-Cilag(1)
	Europe	Epoetin alfa biosimilars(3)	Various
	U.S. & Europe	MIRCERA®(5)	Galenica Group (Galenica)/F. Hoffmann-La Roche Ltd. (Roche)

EPOGEN®	U.S.	MIRCERA®(5)	Galenica/Roche
Sensipar®(6)/ Mimpara®	U.S. & Europe	Active Vitamin D analogs	Various

Product	Territory	Competitor Marketed Product	Competitors
XGEVA®	U.S. & Europe	Zoledronate generics	Various
	U.S. & Europe	Alendronate generics	Various
Prolia®	U.S. & Europe	Raloxifene generics	Various
	U.S. & Europe	Zoledronate generics	Various
	U.S.	Granix®	Teva
NEUPOGEN®	U.S.	Zarxio™	Sandoz
	Europe	Filgrastim biosimilars[3]	Various
Vectibix®	U.S. & Europe	Erbitux®	Eli Lilly/Bristol-Myers Squibb Company (BMS); Merck KGaA
	U.S. & Europe	Avastin®	Genentech, Inc. (a Member of the Roche Group)
Nplate®	U.S. & Europe	Promacta®/Revolade®	Novartis
	U.S.	VELCADE®	Millennium Pharmaceuticals, Inc.[7]
Kyprolis®[8]	U.S.	REVLIMID®	Celgene Corporation (Celgene)
	U.S.	POMALYST®	Celgene
Repatha®	U.S. & Europe	PRALUENT®	Regeneron Pharmaceuticals, Inc.

(1) A subsidiary of Johnson & Johnson (J&J).
(2) Dermatology only.
(3) Approved via the EU biosimilar regulatory pathway.
(4) PROCRIT® competes with Aranesp® in the supportive cancer care and pre-dialysis settings.
(5) MIRCERA® competes with Aranesp® in the nephrology segment only.
(6) Teva and Barr Pharmaceuticals have received tentative approval from the FDA for generic versions of Sensipar® that could compete with Sensipar® in the future. There is an injunction prohibiting them from commercializing in the United States until expiration of the Sensipar® patents.
(7) A wholly-owned subsidiary of Takeda Pharmaceutical Company Limited.
(8) Kyprolis® operates in a rapidly growing market in a new therapeutic area where competition is changing rapidly.

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, continue to be focused on reducing the cost of healthcare. Their efforts have only intensified as a result of rising healthcare costs and economic challenges. Drugs, and specialty drugs, such as our products, remain a focus for cost containment by these parties. Government and private payers around the world are being more restrictive regarding the use of our and other biopharmaceutical products, while demanding a greater level of clinical evidence to support the benefit such products bring to patients and the broader healthcare system.

Recent developments have intensified scrutiny of biopharmaceutical companies in the United States. Pricing practices of a few biopharmaceutical companies have increased public media and government scrutiny of our entire industry. Such pricing practices provide greater incentive for government and private payers to limit or regulate the price of drug products and services. At the same time, value assessments of new technology, previously used predominantly outside the United States, are having an impact in the U.S. healthcare environment. Healthcare provider and independent organizations are creating their own value assessments of biopharmaceutical drugs for comparison to manufacturer pricing. While these organizations do not set drug prices, they seek to influence pricing and payer and provider decision-making by making their assessments public. These developments create greater pressure on the access, pricing 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 specified rebates or discounts on the products we sell to certain government funded programs, including Medicare and Medicaid, which have increased over time. The Patient Protection and Affordable Care Act (ACA), enacted in 2010, increased many of

the mandatory discounts and rebates required of us and

imposed a new Branded Prescription Pharmaceutical Manufacturers and Importers (BPD) fee payable each year by us and other manufacturers. In addition, Medicare currently requires a 2% reduction to Medicare payment rates to providers due to federal budget cuts referred to as "sequestration". Such changes have had, and are expected to continue to have, a material adverse impact on our business.

Further efforts to reduce government healthcare program costs could also affect us and our industry. Examples of proposals that have been discussed and debated but not yet enacted include state ballot initiatives designed to require pharmaceutical manufacturers to publicly report proprietary pricing information or state legislative efforts to place a maximum price ceiling, or cap, on pharmaceutical products purchased by state agencies. Other 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 payment; and coverage and payment for biosimilars, including the current Medicare biosimilar coverage and payment policies that enable greater utilization versus the branded originators, or other policies that provide easier substitution or reimbursement advantages.

In the U.S. private sector, healthcare providers and payers remain focused on reducing healthcare costs. They continue to institute various cost reduction and containment measures such as more limited benefit designs, tiering of co-pays, stricter usage requirements and higher deductible benefit plans that lower healthcare costs altogether or shift a greater proportion of costs to patients. In the retail pharmacy sector, where the majority of our sales for ENBREL, Sensipar® and Repatha® occur, pharmacy benefit managers (PBMs) and insurers are implementing more rigorous utilization and pricing tools that can reduce Amgen product usage or revenues. PBMs are third-party administrators of prescription drug programs for large employers, health plans and government programs. These customers, known as "plan sponsors," increasingly rely on PBMs to help administer their plans in a cost effective manner and negotiate contracts on their behalf. Consolidation in the market has resulted in three PBMs overseeing approximately 75% and three insurers overseeing approximately 43%, respectively, of total covered lives in the United States. This has allowed each greater market power and negotiating leverage to influence or impact patient drug usage and price. In the case of PBMs, this can include mandating stricter utilization criteria or excluding drugs from their formulary altogether in favor of competitor drugs or alternative treatments. Formulary exclusion effectively encourages the patient and provider to seek alternative treatment or pay 100% of the cost of the drug.

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

These dynamics and recent developments serve to create pressure on the pricing and potential usage of our products, and the industry as a whole. We remain focused on addressing unmet medical needs. We believe the pricing of our medicines reflects the holistic value delivered to patients, providers and payers and is aligned with the investment and risk we undertake to develop medicines as well as fund future scientific innovation. We continue to adapt to these dynamics to successfully bring our medicines to patients. This includes working more closely with payers to address their concerns, delivering robust supporting data packages, and developing mutually beneficial contracting structures. As such, we believe we can successfully deliver the value of our medicines.

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.

9

Manufacturing, Distribution and Raw Materials

Manufacturing

The products we manufacture include both biologics and small molecule drugs. The majority of our products are biologics which are produced in living cells and 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. For additional information regarding manufacturing facilities, see Item 2. Properties.

We perform most of our bulk manufacturing, formulation, fill and finish activities in our Puerto Rico facility and also conduct finish activities in the Netherlands. We also utilize third-party contract manufacturers to supplement the bulk, formulation, fill, and/or packaging of certain Amgen principal products, including ENBREL, Neulasta®, XGEVA®, Sensipar®/Mimpara®, Prolia®, as well as Kyprolis®.

Clinical bulk, formulation, fill and finish manufacturing facilities are operated primarily in our Thousand Oaks, California, and West Greenwich, Rhode Island locations. 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 the United States—principally in Kentucky and 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, 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 of Manufacturing Standards.

Manufacturing Initiatives

We believe we are a leader in manufacturing biologics and our manufacturing capabilities are a competitive advantage. We have multiple ongoing initiatives that are designed to extend this advantage by optimizing our manufacturing network and/or mitigating manufacturing risks while continuing to ensure adequate supply of our products. These initiatives include the licensure of a new formulation and fill facility at our Puerto Rico site; and as part of a risk mitigation strategy, full licensure of our formulation, fill and finish site in Ireland to manufacture our products. Both of these new facilities will require qualification and licensure by various regulatory authorities.

In 2015, we initiated the drug substance conformance campaign to facilitate licensure at our monoclonal antibody manufacturing facility in Singapore. Upon licensure, this facility will expand our capability to manufacture monoclonal antibodies utilizing new technology and innovation. The facility will be fully reconfigurable, providing efficient manufacturing capabilities to help ensure supply of our products worldwide. We have also begun construction on an additional new facility at the site in Singapore to enable the manufacture of the active pharmaceutical ingredient for Kyprolis®.

In addition to these initiatives, we have projects designed to optimize manufacturing asset utilization, to continue our use of third-party contract manufacturers and to maintain a state of regulatory compliance. This includes manufacturing network consolidation initiatives as well as process improvements surrounding manufacturing. See Item 1A. Risk Factors—Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

Raw Materials and Medical Devices

Certain raw materials, medical devices 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 assist in authenticating the source of raw materials, including intermediary materials used in the manufacture of our products, which include verification of the country of origin. These 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, reporting of certain payments and other transfers of value, and distribution of our products.

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, re-evaluate, 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 NDA for small molecule products. We cannot market or promote a new product until our marketing application has been approved by the FDA.

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 "similar." 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 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 seven guidance documents as part of the implementation of the abbreviated approval pathway for biosimilars and four of these have been finalized. The FDA has announced its planned publication of additional draft guidance documents relating to biosimilar interchangeability and biosimilars labeling. As of the end of 2015, one biosimilar application has been approved by the FDA, and 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 the Internet. 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 comprised 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 EU countries, Switzerland, Canada, Australia and Japan, regulatory requirements and approval processes are similar in principle to those in the United States. In the EU, depending on the type of drug for which approval is sought, there are currently two potential tracks for marketing approval, a decentralized and centralized procedure. In the decentralized procedure, identical applications for marketing authorization are submitted simultaneously to the national regulatory agencies. The application is assessed by an initial national agency (Reference Member State) and the subsequent countries that the applicant chooses to seek approval (Concerned Member States). Regulatory review is led by the Reference Member State and acknowledged by the Concerned Member States leading to a single approval 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 a thorough product evaluation, drawing from its scientific resources across Europe. If the drug product is proven to fulfill the requirements for quality, safety and efficacy, the Committee for Medicinal Products for Human Use (CHMP) adopts a positive opinion, which is transmitted to the EC for final approval 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 Japan, additional local clinical trials may be required as part of the drug registration process, which can add to the drug registration timelines.

In the EU, biosimilars have been approved under a specialized pathway of the centralized procedure. As with the U.S. pathway, sponsors of a biosimilar may 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 "similar."

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 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, a number of countries such as China, South Korea and Taiwan may require local clinical trials as part of the drug registration process in addition to the global clinical trials which can add to the drug registration timelines. In most Asian markets, registration timelines are dependent on marketing approval in the United States or EU. However, in some emerging markets in Asia, such as China, the regulatory landscape is evolving and the regulatory timelines can be less predictable.

Post-approval Phase

After approval, we continue to monitor adverse events reported following the use of our products through post marketing routine pharmacovigilance 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 the implementation of signal detection, assessment and communication of adverse events that may be associated with the use of our products. 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 our ESAs, 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 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 (for example, violations regarding improper promotional activity or unlawful payments) contributes to the submission of a false claim.

On December 19, 2012, Amgen announced that 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. 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 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 in the areas of oncology/hematology, cardiovascular disease, inflammation, bone health, nephrology and neuroscience. We take a modality-independent approach to R&D with a focus on biologics. Our discovery research programs may therefore yield targets that lead to the development of human therapeutics delivered as large molecules, small molecules, or other combination or new modalities. For the years ended December 31, 2015, 2014 and 2013, our R&D expenses were $4.1 billion, $4.3 billion and $4.1 billion, respectively.

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

We conduct clinical trial activities using 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 to open clinical sites and to enroll patients in a number of geographic locations. See Government Regulation—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 can 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 where we have products or where 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 the 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 the 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 is a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 15, 2016, 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	
AMG 334	Episodic migraine
Aranesp®	Myelodysplastic syndromes
BLINCYTO®	ALL
ENBREL	Psoriatic arthritis; Rheumatoid arthritis remission
IMLYGIC™	Metastatic melanoma
Kyprolis®	Multiple myeloma
Parsabiv™	SHPT in patients with CKD receiving dialysis
Prolia®	Glucocorticoid-induced osteoporosis
Repatha®	Hyperlipidemia
Romosozumab	Postmenopausal osteoporosis; Male osteoporosis
Vectibix®	mCRC
XGEVA®	Delay or prevention of bone metastases in breast cancer; Cancer-related bone damage in patients with multiple myeloma
Phase 2 Programs	
AMG 157	Asthma; Atopic dermatitis
AMG 181	Inflammatory bowel diseases
AMG 334	Chronic migraine
AMG 520	Alzheimer's disease
AMG 899	Dyslipidemia
BLINCYTO®	Diffuse Large B-Cell Lymphoma (DLBCL)
Omecamtiv mecarbil	Heart failure
XGEVA®	Metastatic non-small cell lung cancer (NSCLC)
Phase 1 Programs	
AMG 211	Various cancer types
AMG 224	Multiple myeloma
AMG 228	Solid tumors
AMG 232	Various cancer types
AMG 301	Migraine
AMG 319	Hematologic malignancies
AMG 330	Acute myeloid leukemia
AMG 357	Autoimmune diseases
AMG 557	Systemic lupus erythematosus
AMG 581	Schizophrenia
AMG 592	Inflammatory diseases
AMG 820	Various cancer types
Kyprolis®	Small-cell lung cancer
Oprozomib	Hematologic malignancies

Phase 3	clinical trials investigate the safety and efficacy of a product candidate 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 a product candidate in a large number of patients who have the disease or condition under study.
Phase 1	clinical trials investigate safety and proper dose ranges of a product candidate in a small number of human subjects.

Phase 3 Product Candidate Program Changes

As of February 12, 2015, we had 15 phase 3 programs. As of February 15, 2016, we had 15 phase 3 programs, as three programs initiated or advanced to phase 3 trials, and three programs were terminated or concluded. These changes are set forth in the following table:

Molecule	Disease / Condition	Program Change
AMG 334	Episodic migraine	Advanced to phase 3
Brodalumab	Psoriasis;	Terminated our participation
	Psoriatic arthritis	Terminated our participation
ENBREL	Psoriatic arthritis;	Initiated phase 3 study
	Rheumatoid arthritis remission	Initiated phase 3 study
Trebananib	First-line ovarian cancer	Terminated

Phase 3 Product Candidate Patent Information

The following table describes our outstanding composition of matter patents that have 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*
AMG 334	U.S.	Polypeptides	2031
Parsabiv™	U.S.	Compound	2030
Romosozumab	U.S.	Polypeptides	2026
	Europe	Polypeptides	2026

* 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.

AMG 334

AMG 334 is a human monoclonal antibody that inhibits the receptor for calcitonin gene-related peptide. It is being evaluated for the prophylaxis of migraine. AMG 334 is being jointly developed with Novartis.

Phase 3 studies in episodic migraine are ongoing, and a phase 2 study in chronic migraine is ongoing.

Aranesp®

Aranesp® is a recombinant human protein agonist of the erythropoietin receptor.

In February 2016, we announced that the randomized, double-blind, placebo-controlled phase 3 ARCADE trial met its primary endpoint of reducing the incidence of red blood cell transfusions in anemic patients with low and intermediate-1 risk MDS.

BLINCYTO®

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

In February 2016, we announced that the phase 3 TOWER study evaluating the efficacy of BLINCYTO® versus standard of care in adult patients with Ph- relapsed or refractory B-cell precursor ALL, met its primary endpoint of improved OS based on the results of a prespecified interim analysis.

A phase 3 study in pediatric patients with high-risk first relapse B-precursor ALL is ongoing. Phase 2 studies in adult patients with relapsed/refractory Philadelphia chromosome-positive (Ph+) and minimal residual disease of ALL are ongoing. A phase 2 study in adult patients with DLBCL is ongoing.

Denosumab

Denosumab is a human monoclonal antibody that inhibits RANKL.

Prolia®

A phase 3 study of Prolia® for the treatment of glucocorticoid-induced osteoporosis is ongoing.

XGEVA®

Phase 3 studies for the delay or prevention of bone metastases in patients with adjuvant breast cancer and prevention of SREs in patients with multiple myeloma are ongoing. A phase 2 study in NSCLC is ongoing.

ENBREL

ENBREL is a fusion protein that inhibits tumor necrosis factor.

A phase 3 study to evaluate ENBREL as a monotherapy for psoriatic arthritis treatment is ongoing. A phase 3 study to evaluate ENBREL as a monotherapy in maintaining remission in rheumatoid arthritis is ongoing.

IMLYGIC™

IMLYGIC™ is an oncolytic immunotherapy derived from HSV-1.

A phase 1b/3 study to evaluate IMLYGIC™ in combination with 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 December 2015, we announced that we submitted to the EMA a Variation to the MAA to expand the indication for Kyprolis® in combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy based on the data from the ENDEAVOR trial.

A phase 3 study, CLARION, evaluating Kyprolis® in combination with melphalan and prednisone compared to bortezomib, melphalan and prednisone in newly diagnosed multiple myeloma is ongoing. A phase 3 study, 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), with weekly dosing in relapsed and refractory multiple myeloma is also underway.

A phase 1b/2 study in small-cell lung cancer is ongoing.

Parsabiv™

Parsabiv™ is a peptide agonist of the human cell surface CaSR. It is being evaluated as an intravenously administered treatment of SHPT.

In September 2015, we announced that we submitted an MAA to the EMA for Parsabiv™ for the treatment of SHPT in adult patients with CKD on hemodialysis.

In November 2015, we announced that the FDA has accepted for review our NDA for Parsabiv™ for the treatment of SHPT in adult patients with CKD on hemodialysis.

Repatha®

Repatha® is a human monoclonal antibody that inhibits PCSK9.

In September 2015, we announced that we submitted an application to the FDA for a single-dosing option for the monthly administration of Repatha®. The PDUFA target action date is July 10, 2016.

In February 2016, we announced that the phase 3 GAUSS-3 trial evaluating Repatha® in patients with high cholesterol who cannot tolerate statins, met its co-primary endpoints.

Additional phase 3 studies to evaluate Repatha® for cardiovascular outcomes, on cognitive function, in subjects with genetic LDL disorders, and with coronary imaging are ongoing.

Romosozumab

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

In September 2015, we and UCB announced that the open label phase 3 STRUCTURE trial met its primary endpoint. Phase 3 studies for the treatment of postmenopausal women with osteoporosis and men with osteoporosis are ongoing.

Vectibix®

Vectibix® is a human monoclonal antibody antagonist of the EGFr.

In June 2015, we announced that results of a phase 3 study evaluating Vectibix® and BSC met its primary endpoint, demonstrating a statistically significant improvement in OS in patients with chemorefractory wild-type KRAS (exon 2) mCRC compared to those patients treated with BSC alone.

AMG 157

AMG 157 is a human monoclonal antibody that inhibits the action of TSLP. It is being evaluated as a treatment for asthma and atopic dermatitis, with phase 2 studies ongoing. AMG 157 is being jointly developed in collaboration with AstraZeneca.

AMG 181

AMG 181 is a human monoclonal antibody that inhibits the action of alpha4/beta7. It is being evaluated as a treatment for ulcerative colitis and Crohn’s disease, with phase 2 studies ongoing. AMG 181 is being jointly developed in collaboration with AstraZeneca.

AMG 520

AMG 520 is a small molecule inhibitor of BACE. It is being evaluated for the prevention of Alzheimer’s disease, with phase 2 studies ongoing. AMG 520 is being jointly developed in collaboration with Novartis.

AMG 899

AMG 899 is a small molecule CETP inhibitor. It is being evaluated for the treatment of dyslipidemia and has completed certain phase 2 studies.

Omecamtiv mecarbil

Omecamtiv mecarbil is a small molecule activator of cardiac myosin. It is being evaluated for the treatment of heart failure. We are developing this product in collaboration with Cytokinetics, Inc. (Cytokinetics).

In October 2015, we announced that phase 2 data in patients with chronic heart failure showed statistically significant improvements in several measures of cardiac function.

Amgen Development of Biosimilars

We continue to collaborate with Allergan to develop and commercialize, on a worldwide basis, four oncology antibody biosimilar medicines. The products our collaboration is pursuing include biosimilar versions of bevacizumab (Avastin®), trastuzumab (Herceptin®), rituximab (Rituxan® / Mabthera®) and cetuximab (Erbitux®).

We are also working to develop biosimilar versions of adalimumab (HUMIRA®) and infliximab (REMICADE®), in addition to three other biosimilar molecules. Our biosimilar product candidates are in varying stages of clinical development as described in the following table:

Biosimilar	Status
adalimumab (HUMIRA®)	BLA accepted by FDA for review MAA submitted to EMA
bevacizumab (Avastin®)	Phase 3 NSCLC study met primary and key secondary endpoints
trastuzumab (Herceptin®)	Phase 3 breast cancer study ongoing
infliximab (REMICADE®)	Phase 1 completed

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.

Kirin-Amgen, Inc. (K-A) is a 50-50 joint venture with Kirin Holdings Company, Limited (Kirin). K-A develops and then out-licenses to third parties certain product rights which have been transferred to this joint venture from Amgen and Kirin.

K-A has given us exclusive licenses to manufacture and market: (i) 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, we pay K-A royalties based on product sales. In addition, we also receive payments from K-A for milestones earned and for conducting certain R&D activities on its behalf. See Part IV—Note 8, Related party transactions, to the Consolidated Financial Statements.

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 and recombinant human erythropoietin under the brand names GRAN®/Grasin®, Peglasta®/Neulasta®/G-Lasta®, NESP®/Aranesp®, ROMIPLATE® and ESPO®, 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.

Pfizer Inc.

The co-promotion term of our ENBREL collaboration agreement with Pfizer in the United States and Canada expired on October 31, 2013, giving us full ownership of ENBREL promotional rights in the United States and Canada while the rights to market ENBREL outside the United States and Canada are reserved to Pfizer. Under the collaboration agreement, Amgen and Pfizer shared in the agreed-upon selling and marketing expenses approved by a joint committee. We paid Pfizer a percentage of annual gross profits on our ENBREL sales in the United States and Canada on a scale that increased with gross profits; however, we maintained a majority share of ENBREL profits. In 2016, we are required to pay Pfizer residual royalties of 10% of annual net ENBREL sales in the United States and Canada. The amounts of such payments are significantly less than what was owed based on the terms of the previous ENBREL profit share. Effective November 1, 2016, there will be no further royalty payments.

Bayer HealthCare Pharmaceuticals Inc.

As a result of our acquisition of Onyx Pharmaceuticals, Inc. (Onyx), we are party to a collaboration with Bayer HealthCare Pharmaceuticals Inc. (Bayer) to jointly develop and commercialize Nexavar® (sorafenib) worldwide, except in Japan. The rights to develop and market Nexavar® in Japan are reserved to Bayer.

In May 2015, we and Bayer amended the terms of the collaboration, 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.

UCB

We are in a collaboration with UCB for the development and commercialization of romosozumab. Under the agreement, we received the rights to commercialize romosozumab for all indications in the United States, Canada, Mexico and Japan. UCB has the rights for all EU members at the time of first regulatory approval, Australia and New Zealand. Prior to commercialization, countries that have not been initially designated will be designated to Amgen or UCB in accordance with the terms of the agreement.

Generally, development costs are shared equally and we will share equally in the worldwide commercialization profits and losses related to the collaboration after accounting for expenses.

DaVita Inc.

We are in a seven-year supply agreement with DaVita that commenced January 1, 2012. Pursuant to this agreement, we will supply EPOGEN® in amounts necessary to meet no less than 90% of DaVita’s and its affiliates’ requirements for ESAs used in providing dialysis services in the United States and Puerto Rico. 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, 2015, Amgen had approximately 17,900 staff members. We consider our staff relations to be good.

Executive Officers of the Registrant

The executive officers of the Company as of February 9, 2016 are set forth below.

Mr. Robert A. Bradway, age 53, has served as a director of the Company since October 2011 and Chairman of the Board of Directors since January 1, 2013. Mr. Bradway has been the Company's President since May 2010 and Chief Executive Officer since May 2012. From May 2010 to May 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 April 2007 to May 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 Norfolk Southern Corporation, a transportation company, since July 2011. He has served on the board of trustees of the University of Southern California since April 2014, and on the advisory board of the Leonard D. Schaeffer Center for Health Policy and Economics at that university since 2012.

Mr. Madhavan ("Madhu") Balachandran, age 65, became Executive Vice President, Operations in August 2012. Mr. Balachandran joined the Company in 1997 and has held leadership positions in engineering, information systems and operations. From October 2007 to August 2012, Mr. Balachandran was Senior Vice President, Manufacturing. From February 2007 to October 2007, Mr. Balachandran was Vice President, Site Operations. From May 2002 to February 2007, Mr. Balachandran was Vice President, Puerto Rico Operations. Prior to 2002, Mr. Balachandran served as Associate Director Capital Projects before his promotion to Director Engineering and then to Vice President, Information Management. Previously, Mr. Balachandran served as Vice President, Engineering at Burroughs Wellcome & Company.

Mr. Jonathan P. Graham, age 55, became Senior Vice President, General Counsel and Secretary in July 2015. Prior to joining the Company, from July 2006 to May 2015, Mr. Graham was Senior Vice President and General Counsel at Danaher Corporation. From October 2004 to June 2006, Mr. Graham was Vice President, Litigation and Legal Policy at General Electric Company. Prior to General Electric Company, Mr. Graham was a partner at Williams & Connolly LLP.

Dr. Sean E. Harper, age 53, became Executive Vice President, Research and Development in February 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 March 2007 to February 2012. Prior to joining the Company, Dr. Harper worked for five years at Merck Research Laboratories.

Mr. Anthony C. Hooper, age 61, became Executive Vice President, Global Commercial Operations in October 2011. From March 2010 to October 2011, Mr. Hooper was Senior Vice President, Commercial Operations and President, U.S., Japan and Intercontinental of BMS. From January 2009 to March 2010, Mr. Hooper was President, Americas of BMS. From January 2004 to January 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.

Mr. Brian McNamee, age 59, became Executive Vice President, Full Potential Initiatives in October 2013. Mr. McNamee joined the Company in June 2001 as Senior Vice President, Human Resources. From November 1999 to June 2001, Mr. McNamee served as Vice President of Human Resources at Dell Computer Corp. From 1998 to 1999, Mr. McNamee served as Senior Vice President, Human Resources for the National Broadcasting Corporation, a division of the General Electric Company. From July 1988 to November 1999, Mr. McNamee held human resources positions at General Electric.

Mr. David W. Meline, age 58, became Executive Vice President and Chief Financial Officer in July 2014. From April 2011 to July 2014, Mr. Meline served as Senior Vice President and Chief Financial Officer at 3M Company. From September 2008 to March 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 was a director of TRW Automotive Holdings, Corp., a supplier of automotive systems, modules and components, from February 2014 until its acquisition by ZF Friedrichshafen AG in May 2015.

Ms. Cynthia M. Patton, age 54, became Senior Vice President and Chief Compliance Officer in October 2012. Ms. Patton joined the Company in 2005. From July 2005 to September 2010, Ms. Patton was Associate General Counsel. From September 2010 to October 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 59, became Senior Vice President, Business Development in March 2014. Mr. Piacquad joined the Company in June 2010. From June 2010 to January 2014, Mr. Piacquad served as Vice President, Strategy and Corporate Development. From January 2014 to March 2014, Mr. Piacquad served as Vice President, Business Development. Prior to joining the Company, from December 2009 to June 2010, Mr. Piacquad was Principal of David A. Piacquad Consulting LLC. From March 2006 to December 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.

Dr. Stuart A. Tross, age 49, became Senior Vice President, Human Resources in October 2013. Dr. Tross joined the Company in April 2006 as Vice President, Human Resources. Prior to joining Amgen, from November 1998 to April 2006, Dr. Tross served in a series of roles for BMS, with his last position being Vice President and Global Head of Human Resources of Mead Johnson Nutrition. Prior to joining BMS, Dr. Tross was a management consultant for Towers Perrin.

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 internet address 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. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties facing our business. The risks described below are not the only ones facing us. 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 principal products are dependent 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. Public scrutiny of the price of drugs and other healthcare costs is increasing and more control over pricing could hurt our ability to price our products based upon their value.

A substantial portion of our U.S. business relies on reimbursement from the U.S. federal government healthcare programs and private insurance plans regulated by the U.S. federal government. (See Item 1. Business—Reimbursement.) Changes to U.S. federal reimbursement policy may come through legislative actions such as the ACA or as a result of regulations implemented by the Centers for Medicare & Medicaid Services (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. Legislative or regulatory changes that decrease the coverage or reimbursement available for our products, require that we pay increased rebates, limit our ability to offer patient co-pay payment assistance or limit the pricing of pharmaceutical products could have a material adverse effect on our business and results of operations. Private payers, including healthcare insurers, PBMs and others, increasingly seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage. 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. Insurers and others are adopting benefit plan changes that shift a greater portion of prescription costs to patients, and some payers may attempt to limit the use of patient co-pay payment assistance programs. Private payers also control costs by imposing restrictions on access to our products, such as requiring prior authorizations or step therapy, and may even choose to exclude coverage entirely. Such discounts, rebates, plan changes, restrictions or exclusions could have a material adverse effect on sales of our affected products.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products to U.S. government healthcare programs. Pricing data that we submit 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 on a monthly and quarterly basis, 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.

Outside the United States, we expect that 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 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.

Our products face substantial competition.

We operate in a highly competitive environment. (See Item 1. Business—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 that 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, are easier to administer, reach the market before our products or that are otherwise competitive with our products. 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.

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

We currently face competition from biosimilars in both Europe and the United States, and we expect to face increasing biosimilar competition in the future. To the extent that governments adopt more permissive approval frameworks and competitors are able to obtain broader or expedited marketing approval for biosimilars, the rate of increased competition for our products could accelerate. Expiration or successful challenge of applicable patent rights could trigger such competition, and we could 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.

In the EU, the EC has granted marketing authorizations for biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued in 2005. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU countries have adopted 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 may impose automatic price reductions upon market entry of the second or third biosimilar competitor.

In the United States, in 2010 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, Zarxio,™ a biosimilar version of NEUPOGEN® from Sandoz, was launched in the United States in 2015. 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. Some companies pursuing development of biosimilars versions of our products may challenge our patents well in advance of the expiration of our material patents. (See Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in present and future intellectual property litigation.) For example, in June 2013, Sandoz filed suit against us, seeking a declaratory judgment that the etanercept product it was developing as a biosimilar to ENBREL did not infringe certain of our patents, and that those patents were also invalid and unenforceable. While that suit was dismissed for lack of subject matter jurisdiction as Sandoz had not yet filed a marketing application with the FDA, Sandoz subsequently announced that its marketing application has now been accepted for review by the FDA. (For information related to our other biosimilars patent litigation, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.) The U.S. pathway includes the option for biosimilar products meeting 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 prescribers or pharmacists to substitute those biosimilars for our 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. While we are unable to predict the precise impact of biosimilars on our products, we expect in the future to face greater competition in the United States as a result of biosimilars and downward pressure on our product prices and sales. This additional competition could have a material adverse effect on our business and results of operations.

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

Our business is subject to extensive regulation by numerous state and federal governmental 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 can manufacture, market and sell our products. Once 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. The sanctions could include the FDA's or foreign regulatory authorities' refusal to approve pending applications, delay in obtaining or withdrawals of approvals, delay or suspension of clinical trials, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties and/or criminal prosecutions.

Obtaining and maintaining regulatory approval has 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. Failure to comply with new laws, regulations or regulatory interpretations could result in significant monetary penalties as well as reputational and other harms. We are unable to predict when and whether any further changes to laws or regulatory policies affecting our business could occur, such as efforts to reform medical device regulation or the pedigree requirements for medical products or to implement new requirements for combination products, 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 (progression-free survival, or 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 OS, 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 attacks 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 ultimately approved Repatha® only for a subset of those patients, citing among other things the absence of positive outcomes data showing that Repatha® prevents cardiovascular events. While our

ongoing phase 3 study is evaluating the ability of Repatha® to prevent cardiovascular events, that study may fail to meet its clinical efficacy endpoints or may identify safety issues with the product. (See We must conduct clinical trials in humans before we can commercialize and sell any of our product candidates or existing products for new indications.) Even if the ongoing outcomes study meets its clinical endpoints, regulators may not approve Repatha® for use beyond the currently approved label indications. 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 comparative products 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, in December 2014, we received accelerated approval for BLINCYTO® for the treatment of patients with Ph- relapsed or refractory B-cell precursor ALL in the United States, with continued approval contingent upon clinical benefit in subsequent trials. BLINCYTO® also received conditional marketing authorization for the treatment of patients with Ph- relapsed or refractory B-cell precursor ALL from the EC in November 2015. 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 requirements of regulators 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, our conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change the products' labeled indications or even withdraw the products 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 requirement 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. For example, our ESA REMS requires applicable healthcare providers and institutions to enroll in the program, receive education about the product and the REMS and document and report certain information to us over time. We are responsible for tracking and documenting certain elements of healthcare provider and institution compliance with the ESA REMS, and we use third-party service providers to assist in the administration of certain portions of our REMS. 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. 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 or other pharmacovigilance requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including monetary 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 has resulted in, and may continue to result in, changes to ESA labeling, our ESA REMS 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 nine products currently manufactured, marketed and sold by other pharmaceutical companies. In many 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, significant questions remain as to how products will be approved under the pathway. (See We currently face competition from biosimilars and expect to face increasing competition in the future.) Delays or uncertainties in the development of such pathways could result in delays or difficulties in getting our 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.

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 a commercial product. 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 more effective than currently available therapies in treating a specified condition or illness;
- the product candidate is not cost effective in light of existing therapeutics;
- the product candidate had harmful side effects in humans or animals;
- the necessary regulatory bodies, such as the FDA or EMA, did not approve our product candidate for an intended use;
- the product candidate was not economical for us to manufacture and commercialize;
- the biosimilar product candidate fails to demonstrate the requisite biosimilarity to the applicable reference product, or is otherwise determined to be unacceptable for purposes of safety or efficacy, to gain approval;
- other parties have or may have proprietary rights relating to our product candidate, such as patent rights, and will not let us sell it on reasonable terms, or at all;
- we and certain of our licensees, partners or independent investigators may fail to effectively conduct clinical development or clinical manufacturing activities; and
- the pathway to regulatory approval or reimbursement for product candidates is 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 believe 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 can commercialize and sell any of our product candidates or existing products for new indications.

Before we can 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 patients required for clinical trials vary substantially and therefore, 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 subjects

to participate in our clinical trials, particularly if competitors are conducting clinical trials in similar patient populations. Delays 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 for 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 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 subjects and conduct clinical trials on our behalf in accordance with the applicable study protocols and laws and regulations. Further, we rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations. We also may acquire companies that have ongoing clinical trials. These trials may not be conducted to the same standards as ours; however, once an acquisition has been completed we assume responsibility for the conduct of the trial, 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 the independent investigators selected by us or by a company we have acquired, 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 which 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 involve drugs manufactured and marketed by other pharmaceutical companies. These drugs may be administered in a clinical trial 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 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, this 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 these 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, new indications for existing products or maintenance of 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 the clinical trial program 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 also agreed to conduct 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 additional 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 which 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. In addition, Vectibix® is used in combination with a test kit (which is a companion diagnostic device), and 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 gain or maintain regulatory approval or clearance. Where approval of the product and device is sought under a single marketing drug application, the increased complexity of the review process may also 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 failure of the Amgen or third-party studies, or failure of Amgen 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 the addition of new indications for existing products. 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.

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. For example, a Texas hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) has sought to challenge dozens of patents held by pharmaceutical and biotechnology companies, including one of the patents we hold for ENBREL. 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 may 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 product that is alleged to infringe to market prior to a final resolution of the dispute or litigation. The period of time 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 fully recover for 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 generic 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.

Certain of the existing patents on our principal 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 affected 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/science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, and patient communities. Recommendations by government agencies or other groups/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, who 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 in the United Kingdom (UK) 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. 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 for our common stock.

The adoption 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 and our tax returns are periodically examined by various tax authorities. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities, and changes in applicable tax laws, regulations or administrative interpretations thereof. A change to the U.S. tax system, such as a change to the taxation of income earned outside the United States including credits allowed for foreign taxes, a change to the tax system in a jurisdiction where we have significant operations, such as Puerto Rico, or changes in tax law in the United States or other jurisdictions where we do business, could have a material and adverse effect on our business and on the results of our operations.

We 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 the proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug application 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 the effects of health emergencies, natural disasters, or otherwise.

These events could negatively impact our ability to satisfy demand for our products, which could have a material adverse effect on our product use and sales and our business and results of operations. 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 which 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 or continue to experience these or other shortages in the future resulting in delayed shipments, supply constraints, contract disputes and/or stock-outs of our products.

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 are using 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, natural disasters, or otherwise;
•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 or 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 a new manufacturing plant and it can take longer than three years to qualify and license a new contract manufacturer. In 2015, we initiated the drug substance conformance campaign to facilitate licensure at our monoclonal antibody manufacturing facility in Singapore. This Singapore facility will utilize a novel manufacturing technology that has not been previously approved by the FDA or other regulatory authorities. We have also begun construction on an additional new facility at the site in Singapore to enable the manufacture of the active pharmaceutical ingredient for Kyprolis®. These facilities in Singapore will require licensure by various regulatory authorities. If we are unable to obtain needed licenses for either of these facilities 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 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 they 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, supply constraints, 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, the 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.

We perform a substantial amount of our commercial manufacturing activities at our Puerto Rico manufacturing facility and a substantial amount of our clinical manufacturing activities at our Thousand Oaks, California manufacturing facility; if significant disruptions or production failures occur at the Puerto Rico facility, we may not be able to supply these products or, at the Thousand Oaks facility, we may not be able to continue our clinical trials.

We currently perform all of the formulation, fill and finish for NEUPOGEN®, Aranesp®, EPOGEN®, Prolia® and XGEVA® and substantially all of the formulation, fill and finish operations for Neulasta® and ENBREL at our manufacturing facility in Juncos, Puerto Rico. We also currently perform all of the bulk manufacturing for Neulasta®, NEUPOGEN® and Aranesp®, all of the purification of bulk EPOGEN® material and substantially all of the bulk manufacturing for Prolia® and XGEVA® at this facility. We perform substantially all of the bulk manufacturing and formulation, fill and finish, and packaging for product candidates to be used in clinical trials at our manufacturing facility in Thousand Oaks, California. The global supply of our products and product candidates 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 June 2015, Puerto Rico's Governor stated that the Puerto Rico government, which includes certain government entities, is unable to pay its roughly $72 billion in debt, and since that time, Puerto Rico failed to make certain debt payments. In September 2015, the Puerto Rico government released a Fiscal and Economic Growth Plan (FEGP), a proposal for economic growth and reform measures that also included recommendations for debt restructuring. Due to a deteriorating liquidity position, the Governor issued an executive order in December 2015, providing for certain extraordinary liquidity measures such as deferral of tax refunds, stretching of payments to suppliers and the implementation of a "clawback" of revenues assigned to certain government entities in order to make payments on general obligation bonds and provide essential government services. On January 18, 2016, the Puerto Rico government revised the FEGP to reflect larger government financing gaps in the near and long term as well as the government's deteriorating liquidity position. The Puerto Rico government is currently in negotiations with creditors to restructure the government's debt, and litigation has commenced with certain bond insurers over failure to make certain debt payments. If the Puerto Rico government is not able to restructure the debt obligations or get forbearance on debt payments, it could impact 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 migration of workers from Puerto Rico to the mainland United States, and make it more expensive or difficult for us to operate in Puerto Rico.

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

The substantial majority of our U.S. product sales is made to three pharmaceutical product wholesaler distributors: AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation. 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, which have experienced significant consolidation. Two organizations, DaVita and Fresenius Medical Care North America (Fresenius), own or manage a large number of the outpatient dialysis facilities located in the United States and account for approximately 70% of all EPOGEN® sales. Due to this concentration, these entities have substantial purchasing leverage, which may put pressure on our pricing by their potential ability to extract price discounts on our products or fees for other services, correspondingly negatively impacting our bargaining position and profit margins. In addition, decisions by these entities to purchase less or none of our products in favor of competitive products can have a material adverse effect on our business and results of operations due to their purchasing volume.

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.

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

We have an ongoing process of evaluating potential merger, acquisition, partnering and in-license opportunities that we expect will contribute to our future growth and expand our geographic footprint, product offerings and/or our R&D pipeline. Acquisitions 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. Failures or difficulties in integrating or retaining new personnel or in integrating the operations of the businesses that 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 us incurring asset impairment or restructuring charges. For example, on October 1, 2013, we acquired Onyx, a biopharmaceutical company with several currently marketed products as well as pipeline candidates progressing through the development process, and failures or difficulties in the integration of Onyx could result in a material adverse impact on our business and results of operations.

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 into 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 that we partner with or acquire in emerging markets. (See We must conduct clinical trials in humans before we can 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 an evolving legal and regulatory environment. These legal and operational challenges along with governmental 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 the 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 that we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention and 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 are now operating under a Corporate Integrity Agreement (CIA) 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 CIA also provides for an independent third-party review organization to assess and report on our compliance program. While we expect to fully comply with all of our obligations under the CIA, the failure to do so could result in substantial penalties and our being excluded from government healthcare programs. We may also be subject to actions by governmental entities, including those not participating in the settlement, and may in the future become subject to claims by other parties, in each case with respect to the alleged conduct which is the subject of the settlement. We may see new governmental 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.

We are increasingly dependent on information technology systems, infrastructure and data security.

We are increasingly dependent upon information technology systems, infrastructure and data security. The multitude and complexity of our computer systems and the potential value of our data make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data including intellectual property, trade secrets or personal information belonging to the Company, its patients, customers or other business partners may be exposed to unauthorized persons or to the public. As a global biotechnology company, our systems are subject to frequent cyber-attacks. These attacks are growing in their frequency, sophistication and intensity, and are becoming increasingly difficult to detect. They are often carried out by motivated, well-resourced, skilled and persistent actors including nation states, organized crime groups and "hacktivists." Cyber-attacks could include the deployment of harmful malware and key loggers, a denial-of-service attack, a malicious website, the use of social engineering and other means to affect the confidentiality, integrity and availability of our information technology systems, infrastructure and data. Our key business partners face similar risks and any security breach of their systems could adversely affect our security posture. Although in the past we have experienced cyber-attacks and intrusions into our computer systems, we do not believe that such attacks have had a material adverse effect on our operations. While we continue to invest heavily in the protection of our critical or sensitive data and information technology, there can be no assurance that our efforts will prevent or detect service interruptions or breaches in our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us.

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 Sheet. 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 the sale 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 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 can have an immediate and rapid impact on our stock price, whether or not our operating results are materially impacted.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

As of December 31, 2015, we owned or leased approximately 200 properties. The locations and primary functions of significant properties are summarized in the following table:

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

We believe that our facilities are suitable for their intended use 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 on 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 our 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, 2016, there were approximately 6,809 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, 2015	High	Low
Fourth quarter	$164.58	$140.23
Third quarter	$176.59	$132.24
Second quarter	$169.17	$151.60
First quarter	$170.10	$150.01
Year ended December 31, 2014		
Fourth quarter	$171.64	$130.45
Third quarter	$144.01	$115.39
Second quarter	$126.07	$110.29
First quarter	$127.47	$113.48

Performance graph

The following graph shows the value of an investment of $100 on December 31, 2010, 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, 2010

	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015
Amgen (AMGN)	100.00	118.23	161.10	216.72	308.43	320.68
Amex Biotech (BTK)	100.00	84.16	119.17	179.67	265.76	296.03
Amex Pharmaceutical (DRG)	100.00	112.91	129.74	170.24	198.46	206.75
S&P 500 (SPX)	100.00	102.10	118.23	156.11	177.46	179.90

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, 2015, 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	709,600	$140.92	709,600	$5,000,000,000
November 1 - November 30	339,608	$158.37	339,608	$4,946,215,002
December 1 - December 31	188,807	$158.38	188,807	$4,916,311,000
	1,238,015	$148.37	1,238,015	
January 1 - December 31	11,990,992	$154.49	11,990,992	

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

(2) In October 2015, our Board of Directors authorized an increase that resulted in a total of $5.0 billion available under the stock repurchase program.

Dividends

For the years ended December 31, 2015 and 2014, 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 Statement of Income Data:	2015	2014	2013	2012	2011
	(In millions, except per share data)				
Revenues:					
Product sales	$20,944	$19,327	$18,192	$16,639	$15,295
Other revenues	718	736	484	626	287
Total revenues	21,662	20,063	18,676	17,265	15,582
Operating expenses:					
Cost of sales	4,227	4,422	3,346	3,199	2,708
Research and development	4,070	4,297	4,083	3,380	3,167
Selling, general and administrative	4,846	4,699	5,184	4,814	4,499
Other[1]	49	454	196	295	896
Net income	6,939	5,158	5,081	4,345	3,683
Diluted earnings per share	9.06	6.70	6.64	5.52	4.04
Dividends paid per share	3.16	2.44	1.88	1.44	0.56
	As of December 31,				
Consolidated Balance Sheet Data:	2015	2014	2013	2012	2011
	(In millions)				
Total assets	$71,576	$69,009	$66,125	$54,298	$48,871
Total debt[2]	31,556	30,715	32,128	26,529	21,428
Total stockholders' equity[3]	28,083	25,778	22,096	19,060	19,029

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 impact 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.

(1) In 2011, we recorded a $780 million legal settlement charge ($705 million, net of tax) in connection with an agreement in principle to settle allegations related to our sales and marketing practices.

(2) See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements for discussion of our financing arrangements. In addition, in 2012 and 2011, we issued $5.0 billion and $10.5 billion, respectively, aggregate principal amount of notes. In 2012, we repaid $123 million of Other notes. In 2011, we repaid our 0.125% Convertible Notes of $2.5 billion.

(3) Throughout the five years ended December 31, 2015, we had a stock repurchase program authorized by the Board of Directors through which we repurchased $1.9 billion, $0.2 billion, $0.8 billion, $4.7 billion and $8.3 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 accounting principles generally accepted in the United States (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 and 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 committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology. Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. 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 include ENBREL, Neulasta®, Aranesp®, EPOGEN®, Sensipar®/Mimpara®, XGEVA®, Prolia® and NEUPOGEN®. For additional information about our products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products.

In 2015, we advanced our strategy, by delivering strong financial performance across the business, advancing our innovative pipeline and branded biosimilar programs, developing improved biologic drug delivery systems, transforming our business to a more focused operating model and returning capital to shareholders.

- Financial performance was strong, as total revenues and product sales increased 8% driven by strong performance across the portfolio except EPOGEN® and NEUPOGEN® which both decreased by 9%. Net income and diluted EPS increased by 35%, driven by higher total revenue and lower operating expenses. Cash flows from operating activities grew 6% to $9.1 billion, driven by higher operating income, enabling us to grow the business and invest for the future.
- Our progress can also be seen in six innovative new launches - four in oncology and two in cardiovascular disease. For example, we continued to expand indications for our products, including for Kyprolis® , which is now the only approved therapy for relapsed or refractory multiple myeloma with proven efficacy as a single agent, doublet or triplet combination, that is offered in a variety of doses to meet individual patient needs.
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Our pipeline continues to advance with the recent regulatory submissions for Parsabiv,™ positive phase 3 data for romosozumab (in collaboration with UCB), phase 2 data for AMG 334 (in collaboration with Novartis) and phase 2b data for omecamtiv mecarbil (in collaboration with Cytokinetics). In 2015, we also continued to advance our biosimilar program, including the filing for global regulatory approval for ABP 501, biosimilar adalimumab (HUMIRA®) and phase 3 data for ABP 215, biosimilar bevacizumab (Avastin®).

- We continue to innovate with patient- and provider-friendly delivery systems to differentiate our products. The Neulasta® Onpro™ kit was approved by the FDA at the end of 2014 and now represents approximately one fourth of our U.S. Neulasta® business. We also submitted applications to regulators, including the FDA and EMA, for a single-dosing option for the monthly administration of Repatha®.
- In 2015, we continued to execute the transformation and process improvement efforts announced in 2014. As part of these efforts, we committed to a more focused operating model. Our transformation and process improvement efforts across the Company have enabled us to reallocate resources to fund many of our innovative pipeline and growth opportunities to deliver value to patients and shareholders.
- Finally, we continued returning capital to shareholders in 2015 through the payment of dividends and stock repurchases. We paid dividends of $0.79 per share of common stock in each of the four quarters of 2015, representing a 30% increase over the quarterly dividend paid in each of the four quarters of 2014. In December 2015, we declared a dividend of $1.00 per share of common stock for the first quarter of 2016, payable in March 2016, representing a 27% increase over the quarterly dividends paid in 2015. We also repurchased 12 million shares of our common stock throughout 2015 at an aggregate cost of $1.9 billion. As of December 31, 2015, $4.9 billion remained available under the Board of Directors-approved stock repurchase program.

We believe that we are uniquely positioned for the opportunities arising in biology and to deliver our strategy focusing on the areas of oncology/hematology, cardiovascular disease, inflammation, bone health, nephrology and neuroscience. We have near- and long-term opportunities ahead, including: (i) successfully executing on new product launches, (ii) advancing our robust pipeline with new innovative biologics and new delivery systems, (iii) the development, approval and launch of our biosimilars and (iv) advancing the next-generation manufacturing of high quality biologics. We expect our legacy products to continue to generate significant cash flows. In addition, we continue to focus on collaborating with innovators and value-creating business development activities to expand our approach to deliver significant impact for patients and advance programs where there remains high unmet medical need. Finally, we continue to expand into new geographic growth markets, enabling us to be present in over 100 countries.

Our business will continue to face various challenges. Certain of our products will face increasing competitive pressure as a result of competitive product launches, including from biosimilars. 2016 is the first full year we are competing without patent protection on several of our principal products in the United States. 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.

Current global economic conditions also pose challenges to our business, including continued pressure to reduce healthcare expenditures. Efforts to reduce healthcare costs are being made by third-party payers including governments and private payers. In the United States, various actions have been taken aimed at reducing healthcare spending. The continuing prominence of U.S. budget deficits increases the risk that taxes, fees, rebates, or other federal measures that would further reduce our revenues or increase our expenses may be enacted. As a result of global economic conditions, as well as public and private health care provider focus, the industry continues to experience significant pricing pressures and other cost containment measures.

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. The discovery and development of safe and effective new products, as well as the development of additional indications for existing products, are necessary for the continued strength of our business. We must develop new products over time in order to offset revenue losses when products lose their exclusivity or competing products are launched, as well as in order to provide for revenue and earnings growth. 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.

Finally, our product sales can be affected by wholesaler and end-user buying patterns. These effects can cause fluctuations in quarterly product sales and have generally not been significant when comparing full-year product performance to the prior year.

See Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products and Part I, Item 1A. Risk Factors for further discussion of certain of the factors that could impact our future product sales.

Selected financial information

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

	Year ended December 31, 2015	Change	Year ended December 31, 2014
Product sales:			
U.S.	$16,523	12 %	$14,732
Rest of world (ROW)	4,421	(4)%	4,595
Total product sales	20,944	8 %	19,327
Other revenues	718	(2)%	736
Total revenues	$21,662	8 %	$20,063
Operating expenses	$13,192	(5)%	$13,872
Operating income	$8,470	37 %	$6,191
Net income	$6,939	35 %	$5,158
Diluted EPS	$9.06	35 %	$6.70
Diluted shares	766	(1)%	770

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.

U.S. product sales for 2015 increased across the portfolio except for EPOGEN® and NEUPOGEN®, which declined 9% and 5%, respectively. The U.S. increase was driven primarily by increases in net selling prices. The decrease in ROW product sales for 2015 reflects unfavorable changes in foreign exchange rates and declines in net selling prices, offset partially by unit demand growth.

The decrease in operating expenses for 2015 was driven primarily by savings from transformation and process improvement efforts, higher restructuring charges in the prior year and favorable changes in foreign currency exchange rates, offset partially by increased support for launch products.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is offset partially by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material in 2015, 2014 or 2013.

Results of Operations

Product sales

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

	Year ended December 31, 2015	Change		Year ended December 31, 2014	Change		Year ended December 31, 2013
ENBREL	$5,364	14	%	$4,688	3	%	$4,551
Neulasta®	4,715	3	%	4,596	5	%	4,392
Aranesp®	1,951	1	%	1,930	1	%	1,911
EPOGEN®	1,856	(9	)%	2,031	4	%	1,953
Sensipar®/Mimpara®	1,415	22	%	1,158	6	%	1,089
XGEVA®	1,405	15	%	1,221	20	%	1,019
Prolia®	1,312	27	%	1,030	38	%	744
NEUPOGEN®	1,049	(9	)%	1,159	(17	)%	1,398
Other products	1,877	24	%	1,514	33	%	1,135
Total product sales	$20,944	8	%	$19,327	6	%	$18,192
Total U.S.	$16,523	12	%	$14,732	5	%	$14,045
Total ROW	4,421	(4	)%	4,595	11	%	4,147
Total product sales	$20,944	8	%	$19,327	6	%	$18,192

Future sales of our products will depend, in part, on the factors discussed in the Overview, Part 1—Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition, Part 1—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 1—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, 2015	Change		Year ended December 31, 2014	Change		Year ended December 31, 2013
ENBREL — U.S.	$5,099	16	%	$4,404	3	%	$4,256
ENBREL — Canada	265	(7	)%	284	(4	)%	295
Total ENBREL	$5,364	14	%	$4,688	3	%	$4,551

The increase in ENBREL sales for 2015 was driven primarily by an increase in net selling price offset partially by the impact of competition.

The increase in ENBREL sales for 2014 was driven primarily by an increase in net selling price offset partially by unfavorable changes in wholesaler and, based on prescription data, end-user inventories.

Neulasta®

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

	Year ended December 31, 2015	Change		Year ended December 31, 2014	Change		Year ended December 31, 2013
Neulasta® — U.S.	$3,891	7	%	$3,649	4	%	$3,499
Neulasta® — ROW	824	(13	)%	947	6	%	893
Total Neulasta®	$4,715	3	%	$4,596	5	%	$4,392

The increase in global Neulasta® sales for 2015 was driven primarily by an increase in net selling price in the United States, offset partially by unfavorable changes in foreign currency exchange rates. As of the end of December 2015, the Neulasta® Onpro™ kit represents approximately one fourth of our U.S. Neulasta® business.

In December 2014, the FDA granted approval of the Neulasta® Onpro™ kit which enables the healthcare provider to initiate administration of Neulasta® on the same day as chemotherapy—with delivery of the patient's full dose of Neulasta® the day following chemotherapy administration, consistent with the Neulasta® prescribing information.

The increase in global Neulasta® sales for 2014 was driven primarily by an increase in net selling price in the United States.

Our final material U.S. patent for pegfilgrastim (Neulasta®) expired in October 2015. On December 17, 2014, Apotex, Inc. (Apotex) announced that the FDA accepted for filing its application, under the abbreviated pathway, for pegfilgrastim, a biosimilar version of Neulasta®. Therefore, we expect to face competition in the United States, which over time may have a material adverse impact on Neulasta® sales. For discussion of ongoing litigation between us and Apotex, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

Future Neulasta® sales will also depend, in part, on the development of new protocols, tests and/or treatments for cancer and/or new chemotherapy treatments or alternatives to chemotherapy that may have reduced and may continue to reduce the use of chemotherapy in some patients.

Aranesp®

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

	Year ended December 31, 2015	Change	Year ended December 31, 2014	Change	Year ended December 31, 2013
Aranesp® — U.S.	$900	13 %	$794	6 %	$747
Aranesp® — ROW	1,051	(7)%	1,136	(2)%	1,164
Total Aranesp®	$1,951	1 %	$1,930	1 %	$1,911

The increase in global Aranesp® sales for 2015 was driven by unit demand growth, including a shift from EPOGEN® in the United States, offset partially by unfavorable changes in foreign currency exchange rates and a decrease in net selling price.

The increase in U.S. Aranesp® sales for 2014 was driven by an increase in net selling price and, to a lesser extent, unit demand growth. The decrease in ROW Aranesp® sales for 2014 reflects a decrease in net selling price offset partially by unit demand growth in international markets.

Supplementary protection certificates issued by certain countries relating to our European patent for darbepoetin alfa (Aranesp®) expire in June 2016. See Part 1, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents.

EPOGEN®

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

	Year ended December 31, 2015	Change	Year ended December 31, 2014	Change	Year ended December 31, 2013
EPOGEN® — U.S.	$1,856	(9)%	$2,031	4 %	$1,953

The decrease in EPOGEN® sales for 2015 was driven by a decline in unit demand resulting from competition and a shift in dialysis sales to Aranesp®, offset partially by an increase in net selling price. The decline in EPOGEN® sales accelerated in the second half of 2015 to 37% in the fourth quarter 2015 as compared to the fourth quarter in 2014.

The increase in EPOGEN® sales for 2014 was driven by an increase in net selling price offset partially by a decline in unit demand.

Our final material U.S. patent for EPOGEN® expired in May 2015. We face competition in the United States, which over time may have a material adverse impact on EPOGEN® sales. Currently, in the United States, EPOGEN® and Aranesp® compete with MIRCERA®, which Roche began selling in October 2014 and, as of May 2015, licensed commercialization rights in the United States to Galenica. Simultaneously, Galenica entered into an agreement to supply MIRCERA® to Fresenius, which provides treatment to a significant portion of U.S. dialysis patients. On

December 16, 2014, Hospira, Inc. (Hospira), a subsidiary of Pfizer,

submitted a BLA to the FDA for Retacrit,™ a proposed biosimilar to EPOGEN®. For discussion of ongoing litigation between us and Hospira, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

Sensipar®/Mimpara®

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

	Year ended December 31, 2015	Change		Year ended December 31, 2014	Change		Year ended December 31, 2013
Sensipar® — U.S.	$1,069	34	%	$796	5	%	$757
Sensipar®/Mimpara® — ROW	346	(4	)%	362	9	%	332
Total Sensipar®/Mimpara®	$1,415	22	%	$1,158	6	%	$1,089

The increase in global Sensipar®/Mimpara® sales for 2015 was driven primarily by unit demand growth and an increase in net selling price in the United States. ROW Sensipar®/Mimpara® sales were negatively impacted by changes in foreign currency exchange rates.

The increase in global Sensipar®/Mimpara® sales for 2014 was driven primarily by unit demand growth and an increase in net selling price in the United States, offset partially by unfavorable changes in U.S. wholesaler and, based on prescription data, end-user inventories.

XGEVA®

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

	Year ended December 31, 2015	Change		Year ended December 31, 2014	Change		Year ended December 31, 2013
XGEVA® — U.S.	$1,006	17	%	$857	12	%	$764
XGEVA® — ROW	399	10	%	364	43	%	255
Total XGEVA®	$1,405	15	%	$1,221	20	%	$1,019

The increases in global XGEVA® sales for 2015 and 2014 were driven primarily by unit demand growth.

Prolia®

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

	Year ended December 31, 2015	Change		Year ended December 31, 2014	Change		Year ended December 31, 2013
Prolia® — U.S.	$837	34	%	$625	35	%	$462
Prolia® — ROW	475	17	%	405	44	%	282
Total Prolia®	$1,312	27	%	$1,030	38	%	$744

The increases in global Prolia® sales for 2015 and 2014 were driven primarily by unit demand growth.

NEUPOGEN®

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

	Year ended December 31, 2015	Change		Year ended December 31, 2014	Change		Year ended December 31, 2013
NEUPOGEN® — U.S.	$793	(5	)%	$839	(28	)%	$1,169
NEUPOGEN® — ROW	256	(20	)%	320	40	%	229
Total NEUPOGEN®	$1,049	(9	)%	$1,159	(17	)%	$1,398

The decrease in global NEUPOGEN® sales for 2015 was driven by a decline in unit demand due primarily to the impact of short-acting competition in the United States.

The decrease in global NEUPOGEN® sales for 2014 was driven by the $155-million order from the U.S. government in 2013. Excluding the special order, U.S. and global sales declined 17% and 7%, respectively, which reflected declines in unit demand in the United States, offset partially by the increased sales as a result of acquiring rights to filgrastim in certain international areas effective January 1, 2014.

There is competition in the United States, which we expect will have a material adverse impact on future sales of NEUPOGEN®. On September 3, 2015, Sandoz announced that they launched Zarxio,™ a biosimilar version of NEUPOGEN®, in the United States. On February 17, 2015, Apotex announced that the FDA accepted for filing its application, under the abbreviated pathway, for its biosimilar version of NEUPOGEN®. For discussion of ongoing litigation, see Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

See Part 1, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition and Part IV—Note 18, Contingencies and commitments, to the Consolidated Financial Statements.

Future NEUPOGEN® sales will also depend, in part, on the development of new protocols, tests and/or treatments for cancer and/or new chemotherapy treatments or alternatives to chemotherapy that may have reduced and may continue to reduce the use of chemotherapy in some patients.

Other products

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

	Year ended December 31, 2015	Change		Year ended December 31, 2014	Change		Year ended December 31, 2013
Vectibix® — U.S.	$204	21	%	$168	33	%	$126
Vectibix® — ROW	345	2	%	337	28	%	263
Nplate® — U.S.	317	22	%	260	8	%	241
Nplate® — ROW	208	—	%	209	12	%	186
Kyprolis® — U.S.	467	53	%	306	*		71
Kyprolis® — ROW	45	80	%	25	*		2
Other — U.S.	84	*		3	N/A		—
Other — ROW	207	—	%	206	(16	)%	246
Total other product sales	$1,877	24	%	$1,514	33	%	$1,135
Total U.S. — other products	$1,072	45	%	$737	68	%	$438
Total ROW — other products	805	4	%	777	11	%	697
Total other product sales	$1,877	24	%	$1,514	33	%	$1,135

* Change in excess of 100%

Operating expenses

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

	Year ended December 31, 2015	Change	Year ended December 31, 2014	Change	Year ended December 31, 2013
Operating expenses:					
Cost of sales	$4,227	(4)%	$4,422	32 %	$3,346
% of product sales	20.2 %		22.9 %		18.4 %
% of total revenues	19.5 %		22.0 %		17.9 %
Research and development	$4,070	(5)%	$4,297	5 %	$4,083
% of product sales	19.4 %		22.2 %		22.4 %
% of total revenues	18.8 %		21.4 %		21.9 %
Selling, general and administrative	$4,846	3 %	$4,699	(9)%	$5,184
% of product sales	23.1 %		24.3 %		28.5 %
% of total revenues	22.4 %		23.4 %		27.8 %
Other	$49	(89)%	$454	*	$196

* Change in excess of 100%

Transformation and process improvement

During the second half of 2014, we announced process improvement and transformation initiatives that are enabling us to invest in continuing innovation, expand into new countries and launch new products, while improving our cost structure. This plan includes a restructuring, which is delivering cost savings and funding investments. The restructuring includes reducing our geographic footprint, as well as reducing our staff by 3,500 to 4,000, both of which allow us to reinvest and hire in our strategic areas of focus.

We estimate that this restructuring plan will result in pre-tax accounting charges in the range of $800 million to $900 million, which is less than originally expected due to better than anticipated results from the exit of two of our closed facilities. Restructuring costs to date of $672 million were incurred as of December 31, 2015. During the years ended December 31, 2015 and 2014, we incurred restructuring costs of $114 million and $558 million, respectively. We expect that we will incur most of the remaining estimated costs in 2016 and 2017 in order to support our ongoing transformation and process improvement efforts. Net savings were not significant in 2015 and 2014 due to the investments in new product launch preparations, later stage clinical programs and external business development. Additional information required for our restructuring plan is incorporated herein by reference to Part IV—Note 2, Restructuring and other cost savings initiatives, to the Consolidated Financial Statements.

Cost of sales

Cost of sales decreased to 19.5% of total revenues for 2015, driven primarily by lower royalties, higher net selling prices, manufacturing efficiencies and lower costs related to our restructuring plan. The year ended December 31, 2014, also had a $99-million charge related to the termination of the supply contract with Roche as a result of acquiring the licenses to filgrastim and pegfilgrastim effective January 1, 2014.

Cost of sales increased to 22.0% of total revenues for 2014, driven by acquisition-related expenses that included an increase of $642 million of non-cash amortization of intangible assets acquired in the Onyx acquisition. The year ended December 31, 2014, also included impairment and accelerated depreciation charges pursuant to our restructuring initiative of $104 million as well as the aforementioned $99-million charge related to the termination of the supply contract with Roche.

The excise tax imposed by Puerto Rico on the gross intercompany purchase price of goods and services from our manufacturer in Puerto Rico (Puerto Rico excise tax) is recorded as a cost of sales expense. Excluding the impact of the Puerto Rico excise tax, cost of sales would have been 17.8%, 20.1% and 16.0% of total revenues for 2015, 2014 and 2013, respectively. See Part IV—Note 5, Income taxes, to the Consolidated Financial Statements for further discussion of the Puerto Rico excise tax.

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,		
	2015	2014	2013
DRTS	$997	$1,212	$1,233
Later stage clinical programs	1,876	2,287	1,950
Marketed products	1,197	798	900
Total R&D expense	$4,070	$4,297	$4,083

The decrease in R&D expense for 2015 was driven by decreased costs associated with later stage clinical programs support of $411 million and DRTS of $215 million, offset partially by increased costs associated with marketed products support of $399 million. All categories of R&D spend benefited from savings from transformation and process improvement efforts under our restructuring plan, which were offset partially by increased launch related spend in marketed products, primarily Repatha®. Prior to approval, costs related to our launch products were largely categorized as later stage clinical programs. The 2015 DRTS expenses also included up-front milestone payments related to our collaborations with Xencor, Inc. and Novartis.

The increase in R&D expense for 2014 was driven primarily by increased costs of $326 million associated with Onyx across all categories of R&D spend, as well as increased costs associated with other later stage clinical program support. Overall, costs associated with later stage clinical programs support increased $337 million, offset partially by reduced expenses associated with marketed products support of $102 million and DRTS activities of $21 million. The 2014 DRTS expenses also included a $60 million upfront payment related to our cancer immunotherapy collaboration with Kite Pharma, Inc.

Selling, general and administrative

The increase in Selling, general and administrative (SG&A) expense for 2015 was driven primarily by new product launches offset partially by savings from transformation and process improvement efforts under our restructuring plan. 2014 also included an additional $129 million accrual for the BPD fee as the final regulations accelerated the expense recognition criteria for the fee obligation by one year.

The decrease in SG&A expense for 2014 was driven primarily by the expiration of the ENBREL profit share in October 2013, which reduced expenses by $818 million. That decline was offset partially by the addition of $183 million as a result of the Onyx acquisition, the aforementioned additional accrual for the BPD fee and increased commercial expenses of $109 million in preparation for new product launches.

Historically, under our ENBREL collaboration agreement, we paid Pfizer a percentage of annual gross profits on our ENBREL sales in the United States and Canada on a scale that increased with gross profits. The ENBREL co-promotion term expired on October 31, 2013, and we are required to pay Pfizer residual royalties on a declining percentage of net ENBREL sales in the United States and Canada. The royalty percentage was 12% through October 31, 2014, declining to 11% through October 31, 2015, and 10% through October 31, 2016. Effective November 1, 2016, there will be no further royalty payments.

Other

Other operating expenses for 2015 included $91 million of charges related to legal proceedings, certain charges related to our restructuring initiatives, primarily 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.

Other operating expenses for 2014 included certain charges related to our restructuring plan, primarily separation costs of $377 million. It also included a $46 million write-off of a non-key IPR&D program acquired in a prior year business combination.

Other operating expenses for 2013 included $113 million of adjustments to our estimated contingent consideration liability related to the BioVex Group, Inc. (BioVex) business combination, certain charges related to our other cost savings initiatives of $71 million, which included severance expenses, and $12 million of other charges related primarily to legal proceedings.

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,		
	2015	2014	2013
Interest expense, net	$1,095	$1,071	$1,022
Interest and other income, net	$603	$465	$420
Provision for income taxes	$1,039	$427	$184
Effective tax rate	13.0 %	7.6 %	3.5 %

Interest expense, net

The increase in interest expense, net in 2015 compared with 2014 was due primarily to a higher average amount of fixed rate debt outstanding, offset partially by the impacts of repayment of variable rate debt. The increase in interest expense, net in 2014 compared with 2013 was due primarily to a higher average balance of debt outstanding, offset partially by lower average borrowing rates.

Interest and other income, net

The increase in interest and other income, net for 2015 compared with 2014 was due primarily to higher interest income as a result of higher average cash and investment balances with a modestly higher portfolio yield, offset partially by net losses on sales of interest bearing securities in 2015. The increase in interest and other income, net for 2014 compared with 2013 was due primarily to interest earned as a result of a higher average balance of cash and investments offset partially by a reduction in income realized from the sale of investments in 2014.

Income taxes

The increase in our effective tax rate for 2015 compared with 2014 was due primarily to the unfavorable tax impact of changes in the jurisdictional mix of income and expenses and lower domestic restructuring costs in 2015.

The increase in our effective tax rate for 2014 compared with 2013 is due primarily to two significant events that occurred during 2013. First, the settlement of our examination with the Internal Revenue Service (IRS) for the years ended December 31, 2007, 2008 and 2009, in which we agreed to certain adjustments proposed by the IRS and remeasured our unrecognized tax benefits (UTBs) accordingly, resulting in a benefit of approximately $185 million. Second, because the American Taxpayer Relief Act of 2012 was not enacted until 2013, certain provisions of the Act benefiting the Company’s 2012 federal taxes, including the retroactive extension of the R&D tax credit for 2012, were not recognized in the Company’s 2012 financial results and instead are reflected in the Company’s 2013 financial results. Therefore, our effective tax rate for 2013 included an additional $70 million benefit for the full-year 2012 R&D tax credit. The increase was offset partially by the favorable tax impact of changes in the jurisdictional mix of income and expenses.

The effective tax rates for 2015, 2014 and 2013 would have been approximately 16.4%, 12.8% and 9.2%, respectively, without the impact of the tax credits associated with the Puerto Rico excise tax.

As permitted under U.S. GAAP, we do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be invested indefinitely outside the United States.

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

Financial Condition, Liquidity and Capital Resources

Selected financial data was as follows (in millions):

	December 31,	
	2015	2014
Cash, cash equivalents and marketable securities	$31,382	$27,026
Total assets	$71,576	$69,009
Current portion of long-term debt	$2,250	$500
Long-term debt	$29,306	$30,215
Stockholders' equity	$28,083	$25,778

We intend to continue to 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 in 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 $0.47 per share of common stock in 2013, increased our quarterly cash dividend by 30% to $0.61 per share of common stock in 2014 and increased our quarterly cash dividend by 30% to $0.79 per share of common stock in 2015. In December 2015, the Board of Directors declared a dividend of $1.00 per share of common stock for the first quarter of 2016, an increase of 27%, to be paid in March 2016.

We have also returned capital to stockholders through our stock repurchase program. During the first quarter of 2013, we spent $832 million to repurchase shares of our common stock. During the fourth quarter of 2014, we repurchased $153 million of common stock, of which $138 million was paid in cash by December 31, 2014. During 2015, we repurchased $1.9 billion of common stock. As of December 31, 2015, $4.9 billion remained available under the Board of Directors-approved stock repurchase program.

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 our syndicated credit facilities and access to other domestic and foreign debt markets and equity markets. With respect to our U.S. operations, we believe that existing funds intended for use in the United States; cash generated from our U.S. operations, including intercompany payments and receipts; and existing sources of and access to financing (collectively referred to as "U.S. funds") are adequate to continue to meet our U.S. obligations (including our plans to pay dividends and repurchase stock with U.S. funds) for the foreseeable future. See Part I, Item 1A. Risk Factors—Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

A significant portion of our operating cash flows is dependent on the timing of payments from our customers located in the United States and, to a lesser extent, our customers outside the United States, which include government-owned or -supported healthcare providers (government healthcare providers). Payments from these government healthcare providers are dependent in part on the economic stability and creditworthiness of their applicable country. Historically, some payments from a number of European government healthcare providers have extended beyond the contractual terms of sale, and regional economic uncertainty continues. In particular, credit and economic conditions in Southern Europe, particularly in Spain, Italy, Greece and Portugal, continue to adversely impact the timing of collections of our trade receivables in this region. As of December 31, 2015 and 2014, accounts receivable in these four countries totaled $222 million and $223 million, respectively. Of these receivables, $127 million and $124 million were past due as of December 31, 2015 and 2014, respectively. Although economic conditions in this

region may continue to affect the average length of time it takes to collect payments, to date we have not incurred any significant losses related to these receivables; and the timing of payments in these countries has not had nor is it currently expected to have a material adverse impact on our overall operating cash flows. However, if government funding for healthcare were to become unavailable in these countries or if significant adverse adjustments to past payment practices were to occur, we might not be able to collect the entire balance of these receivables. We will continue working closely with these customers, monitoring the economic situation and taking appropriate actions as necessary.

Cash, cash equivalents, and marketable securities

Of our cash, cash equivalents and marketable securities totaling approximately $31.4 billion as of December 31, 2015, approximately $29.0 billion was generated from operations in foreign tax jurisdictions and is intended to be invested indefinitely outside the United States. Under current tax laws, if these funds were repatriated for use in our U.S. operations, we would be required to pay additional income taxes at the tax rates then in effect.

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.

Financing arrangements

The current and noncurrent portions of our long-term borrowings at December 31, 2015, were $2.3 billion and $29.3 billion, respectively. The current and noncurrent portions of our long-term borrowings at December 31, 2014, were $0.5 billion and $30.2 billion, respectively. As of December 31, 2015, Standard & Poor's Financial Services LLC (S&P), Moody's Investor Service, Inc. (Moody's) and Fitch, 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 and would affect the interest rate paid under our Term Loan Credit Facility.

During the years ended December 31, 2015, 2014 and 2013, we issued long-term debt with aggregate principal amounts of $3.5 billion, $4.5 billion, and $8.1 billion, respectively. During the years ended December 31, 2015, 2014 and 2013, we repaid debt of $2.4 billion, $5.6 billion, and $3.4 billion, respectively. For information regarding specific issuances and repayments of debt, see Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements.

To achieve a desired mix of fixed and floating interest 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, 2015 and 2014, we had interest rate swap contracts with aggregate notional amounts of $6.65 billion. See Part IV—Note 14, Financing arrangements, and Note 17, Derivative instruments, to the Consolidated Financial Statements for further discussion of our interest rate swap contracts.

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 to U.S. dollars. These cross-currency swap contracts qualify and are designated as cash flow hedges. As of December 31, 2015 and 2014, we had cross-currency swap contracts with aggregate notional amounts of $2.7 billion. See Part IV—Note 17, Derivative instruments, to the Consolidated Financial Statements for further discussion of our cross-currency swap contracts.

As of December 31, 2015, 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. At December 31, 2015 and 2014, we had no amounts outstanding under our commercial paper program.

In July 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. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.1% based on our current credit rating. Generally, we would be charged interest at LIBOR plus 0.9% for any amounts borrowed under this facility. As of December 31, 2015 and 2014, no amounts were outstanding under this facility.

In February 2014, we filed a shelf registration statement with the SEC which allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depository shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depository shares. Under this shelf registration statement, all of the securities available for

issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2017.

In 1997, we established a $400 million medium-term note program under which medium-term debt securities may be offered from time to time with terms to be determined at the time of issuance. As of December 31, 2015 and 2014, no securities were outstanding under this medium-term note program.

Certain of our financing arrangements contain non-financial covenants. In addition, our revolving credit agreement and Term Loan Credit Facility each includes a financial covenant with respect to the level of our borrowings in relation to our equity, as defined. We were in compliance with all applicable covenants under these arrangements as of December 31, 2015.

See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements for further discussion of our financing arrangements.

Cash flows

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

	Years ended December 31,		
	2015	2014	2013
Net cash provided by operating activities	$9,077	$8,555	$6,291
Net cash used in investing activities	(5,547)	(5,752)	(8,469)
Net cash (used in) provided by financing activities	(3,117)	(2,877)	2,726

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 2015 due primarily to improvement in our operating margin and the effective termination of foreign currency contracts that resulted in the receipt of $340 million in cash, offset by the timing of payment to vendors and cash received from customers. Cash provided by operating activities increased during 2014 due primarily to higher revenues, higher operating income, including the impact of the expiration of the ENBREL co-promotion term on October 31, 2013, and improvements in working capital.

Investing

Capital expenditures, which were associated primarily with manufacturing capacity expansions in Singapore, Puerto Rico and Ireland, as well as other site developments, totaled $594 million, $718 million and $693 million in 2015, 2014 and 2013, respectively. We currently estimate 2016 spending on capital projects and equipment to be approximately $700 million.

Cash used in investing activities during the years ended December 31, 2015, 2014 and 2013, also included the cost of acquiring certain businesses, net of cash acquired, which totaled $359 million, $165 million and $9.4 billion, respectively. In addition, during the year ended December 31, 2015 and 2014, $55 million and $285 million, respectively, was used to purchase intangible assets.

Net activity related to marketable securities and restricted investments used $4.4 billion in 2015 and 2014, and provided $1.7 billion in 2013.

Financing

Cash used in financing activities during 2015 was due primarily to the repayment of long-term debt of $2.4 billion, the payment of dividends of $2.4 billion, repurchases of our common stock of $1.9 billion and the settlement of obligations incurred in connection with the acquisitions of businesses of $253 million. These payments were offset partially by net proceeds from the issuance of long-term debt of $3.5 billion. Cash used in financing activities during 2014 was due primarily to the repayment of long-term debt of $5.6 billion, the payment of dividends of $1.9 billion and repurchases of our common stock of $138 million. These payments were offset partially by net proceeds from the issuance of long-term debt of $4.5 billion and net proceeds from the issuance of common stock in connection with the Company’s equity award programs of $186 million. Cash provided by financing activities during 2013 was due primarily to net proceeds from the issuance of long-term debt of $8.1 billion and net proceeds from the issuance of common stock in connection with the Company’s equity award programs of $296 million. These receipts were offset partially by the repayment of long-term debt of $3.4 billion, the payment of dividends of $1.4 billion and repurchases of our common stock of $832 million.

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

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.

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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, 2015				
		Year	Years	Years	Years
Contractual obligations	Total	1	2 and 3	4 and 5	6 and beyond
Long-term debt obligations [1] [2] [3] [4]	$49,786	$3,440	$8,604	$7,364	$30,378
Operating lease obligations	749	127	224	199	199
Purchase obligations [5]	2,817	1,045	745	391	636
UTBs [6]	—	—	—	—	—
Total contractual obligations	$53,352	$4,612	$9,573	$7,954	$31,213

(1) Long-term debt obligations include future interest payments which are included in our financing arrangements at the fixed contractual coupon rates. To achieve a desired mix of fixed and floating interest rate debt, we enter into interest rate swap contracts that effectively convert a fixed rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the life of the respective note. We used an interest rate forward curve at December 31, 2015, in computing net amounts to be paid or received under our interest rate swap contracts which resulted in an aggregate net decrease in future interest payments of $83 million. See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements for further discussion of our interest swap contracts.

(2) Long-term debt obligations include future interest payments under our Term Loan at LIBOR-based variable rates of interest. We used an interest rate forward curve at December 31, 2015, in computing interest payments on this debt obligation. See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements for further discussion of this debt obligation.

(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 pound sterling and euro 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 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 for further discussion of our cross-currency swap contracts.

(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 at December 31, 2015. See Part IV—Note 14, Financing arrangements, to the Consolidated Financial Statements for further discussion of our long-term debt obligations.

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

(6) Liabilities for UTBs (net of foreign tax credits and federal tax benefit of state taxes) and related accrued interest and penalties totaling approximately $2.0 billion at December 31, 2015, 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 acquisitions of Dezima Pharma B.V. (Dezima) and 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, 2015, the maximum amount that may be payable in the future for agreements we have entered into with third parties is approximately $5.0 billion, including $1.6 billion of contingent consideration payments in connection with the acquisitions of Dezima and BioVex. 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 U.S. 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 January 1, 2013	$847	$167	$115	$1,129
Amounts charged against product sales	1,784	3,008	669	5,461
Payments	(1,736)	(2,924)	(682)	(5,342)
Balance as of December 31, 2013	895	251	102	1,248
Amounts charged against product sales	2,499	3,399	688	6,586
Payments	(2,274)	(3,454)	(727)	(6,455)
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

For the years ended December 31, 2015, 2014 and 2013, total sales deductions were 27%, 25% and 23% of gross product sales, respectively. Included in the amounts are immaterial adjustments related to prior-year sales due to changes in estimates. Such amounts represent less than 3% of the aggregate sales deductions charged against product sales in each of the three years ended December 31, 2015.

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. For example, we had managed Medicaid rebate adjustments of $164 million in 2013. Changes in annual estimates related to prior annual periods were less than 3% of the estimated rebate amounts

charged against product sales for the years ended December 31, 2015 and 2014, and less than 10% for the year ended December 31, 2013, including the aforementioned adjustment. A 10% change in our rebate estimate attributable to rebates recognized in 2015 would

have had an impact of approximately $270 million, or approximately 1% of our 2015 product sales and a corresponding impact on our financial condition and liquidity.

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

The Company provides for income taxes based on pretax income and applicable tax rates available in the various jurisdictions in which it operates.

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 benefits recognized in the financial statements on a particular tax position are 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 the Company’s 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 the Company has already recorded the tax benefit in the financial statements. The Company establishes valuation allowances against its 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 financial statements for which payment has been deferred; (ii) expenses for which the Company has already taken a deduction on the tax return, but has not yet recognized the expense in the 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.

The Company is a vertically integrated enterprise with operations in the United States and various foreign jurisdictions. The Company is subject to income tax in the foreign jurisdictions where it conducts activities based on the tax laws and principles of such jurisdictions and the functions, risks and activities performed therein. The Company’s pretax income is therefore attributed to domestic or foreign sources based on the operations performed in each location and the tax laws and principles of the respective taxing jurisdictions. For example, the Company conducts significant operations outside the United States in Puerto Rico pertaining to manufacturing, distribution and other related functions to meet its worldwide product demand. Income from the Company’s operations in Puerto Rico is subject to a tax incentive grant that expires in 2020.

Our effective tax rate reflects the impact of undistributed foreign earnings for which no U.S. income taxes or foreign withholding taxes have been provided because such earnings are intended to be invested indefinitely outside the

United States. Substantially all of this benefit is attributable to the Company's foreign income associated with the Company's operations conducted in Puerto Rico.

If future events, including material changes in cash, working capital and long-term investment requirements necessitate that certain assets associated with these earnings be repatriated to the United States, under current tax laws an additional tax provision and related liability would be required at the applicable income tax rates which could have a material adverse effect on both our future effective tax rate and our financial results.

Our operations are subject to the tax laws, regulations and administrative practices of the United States, U.S. state jurisdictions and other countries in which we do business. Significant changes in these rules could have a material adverse effect on the Company's results of operations. See Part I, Item 1A. Risk Factors—The adoption 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. 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 various contingent consideration obligations incurred or assumed in the acquisitions of businesses (see Part IV—Note 3, Business combinations, and Note 16, Fair value measurement, to the Consolidated Financial Statements) were determined using a combination of valuation techniques. Significant estimates and assumptions required for these valuations included, but were not limited to, the probability of achieving regulatory milestones, product sales projections under various scenarios and discount rates used to calculate the present value of the required payments. These estimates and assumptions are required to be updated in order to revalue these contingent consideration obligations each reporting period. Accordingly, subsequent changes in underlying facts and circumstances could result in changes in these estimates and assumptions, which could have a material impact on the estimated future fair values of these obligations.

We believe the fair values used to record intangible assets acquired and contingent consideration obligations incurred in connection with business combinations are based 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 estimated fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods which could have a material adverse effect on our results of operations.

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

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 at December 31, 2015 and 2014. 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, 2015 and 2014.

Interest rate sensitive financial instruments

Our portfolio of available-for-sale interest-bearing securities at December 31, 2015 and 2014, was comprised 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 $31.0 billion and $26.6 billion at December 31, 2015 and 2014, 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 at December 31, 2015 and 2014, would have resulted in a reduction in the fair values of these securities of approximately $840 million and $700 million, respectively, on these dates. In addition, a hypothetical 100 basis point decrease in interest rates at December 31, 2015 and 2014, would not result in a material effect on income or cash flows in the respective ensuing year.

As of December 31, 2015, we had outstanding debt with a carrying value of $31.6 billion and a fair value of $33.1 billion. As of December 31, 2014, we had outstanding debt with a carrying value of $30.7 billion and a fair value of $33.6 billion. Our outstanding debt was comprised primarily of debt with fixed interest rates as the carrying value of variable rate debt was $2.8 billion and $5.2 billion at December 31, 2015 and 2014, respectively. Changes in interest rates do not affect interest expense or cash flows 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 at December 31, 2015 and 2014, would have resulted in an increase of approximately $2.5 billion 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 and floating interest rate debt, we entered into interest rate swap contracts during 2015 and 2014, which qualified and were designated for accounting purposes as fair value hedges, for certain of our fixed-rate debt. These derivative 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 an aggregate notional amount of $6.65 billion were outstanding at December 31, 2015 and 2014. A hypothetical 100 basis point increase in interest rates relative to interest rates at December 31, 2015 and 2014, would have resulted in reductions in fair values of approximately $290 million and $350 million, respectively, on our interest rate swap contracts on these dates and would not result in a material effect on the related income or cash flows 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, 2015 and 2014, we had outstanding cross-currency swap contracts with aggregate notional amounts of $2.7 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 are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates at December 31, 2015 and 2014, would have resulted in reductions in the fair values of our cross-currency swap contracts of approximately $210 million and $260 million, respectively, but would have no material effect on cash flows or income in the respective ensuing year.

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, 2015, we had outstanding euro and pound sterling denominated debt with a carrying value and fair value of $3.0 billion and $3.3 billion, respectively. As of December 31, 2014, the carrying value and fair value of this debt denominated in foreign currencies was $3.3 billion and $3.7 billion, respectively. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2015, would have resulted in an increase in fair value of this debt of approximately $660 million on this date and a reduction in income in the ensuing year of approximately $610 million, but would have no material effect on the related cash flows in the ensuing year. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2014, would have resulted in an increase in fair value of this debt of approximately $740 million on this date and a reduction in income in the ensuing year of approximately $660 million, but would have no material effect on the related cash flows in the ensuing year. The analysis for this debt does not consider the offsetting impact that hypothetical changes in foreign currency exchange rates would have on the related cross-currency swap contracts which are in place for the majority of the foreign currency denominated debt.

With regard to our $2.7 billion notional amount of cross-currency swap contracts that are designated as cash flow hedges of certain of our debt denominated in euros and pound sterling, as of December 31, 2015 and 2014, 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 approximately $610 million on each of these dates, but would have no material effect on the related cash flows in the respective ensuing years. 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, 2015, we had open foreign currency forward and options contracts, primarily euro-based, with notional amounts of $3.3 billion and $225 million, respectively. As of December 31, 2014, we had open foreign currency forward and options contracts, primarily euro-based, with notional amounts of $3.8 billion and $271 million, respectively. As of December 31, 2015 and 2014, the fair value of these contracts was approximately $140 million and $360 million, respectively. With regard to foreign currency forward and option contracts that were open at December 31, 2015, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2015, would have resulted in a reduction in fair value of these contracts of approximately $650 million on this date and, in the ensuing year, a reduction in income and cash flows of approximately $320 million. With regard to contracts that were open at December 31, 2014, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2014, would have resulted in a reduction in fair value of these contracts of approximately $700 million on this date and, in the ensuing year, a

reduction in income and cash flows of approximately $380 million. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign currency sensitive instruments were designed to offset.

As of December 31, 2015 and 2014, we had open foreign currency forward contracts with notional amounts totaling $911 million and $875 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 at December 31, 2015 and 2014. With regard to these foreign currency forward contracts that were open at December 31, 2015 and 2014, 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, related income or cash flows 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, 2015 and 2014, 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, 2015 and 2014, 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 DISCLOSURES

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, 2015.

Management determined that, as of December 31, 2015, 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, 2015. 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, 2015, 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, 2015.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Amgen Inc.

We have audited Amgen Inc.'s (the "Company") internal control over financial reporting as of December 31, 2015, 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"). Amgen Inc.'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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

In our opinion, Amgen Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Consolidated Balance Sheets as of December 31, 2015 and 2014, and 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, 2015 of Amgen Inc. and our report dated February 16, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California

February 16, 2016

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE OF THE REGISTRANT

Information about our Directors is incorporated by reference from the section entitled ITEM 1 — ELECTION OF DIRECTORS in our Proxy Statement for the 2016 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2015 (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 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 — Board Committees and Charters — 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 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 — Board Committees and Charters — 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, 2015, 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, 2015 (including upon the exercise of options, the vesting of awards of restricted stock units, or RSUs, or when performance units are earned, and related dividend equivalents have been granted).

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	(b) Weighted Average Exercise Price Outstanding Options and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by Amgen security holders:			
Amended and Restated 2009 Equity Incentive Plan[1]	11,313,640	$57.72	47,115,890
Amended and Restated 1991 Equity Incentive Plan[2]	592,948	$50.44	—
Amended and Restated Employee Stock Purchase Plan	—	—	5,045,574
Total Approved Plans	11,906,588	$56.22	52,161,464
Equity compensation plans not approved by Amgen security holders:			
Amended and Restated 1999 Equity Incentive Plan[3]	9,290	$53.10	—
Amended and Restated 1999 Incentive Stock Plan[4]	5,257	$51.79	—
Amended and Restated Assumed Avidia Incentive Equity Plan[5]	518	$1.90	—
Amgen Profit Sharing Plan for Employees in Ireland[6]	—	—	133,550
Total Unapproved Plans	15,065	$50.88	133,550
Total All Plans	11,921,653	$56.19	52,295,014

(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.

The number of outstanding awards under column (a) includes, as of December 31, 2015, (i) 2,188,567 shares issuable upon the exercise of outstanding options with a weighted-average exercise price of approximately $57.72, (ii) 5,237,393 shares issuable upon the vesting of outstanding RSUs (including 213,554 related dividend equivalents), and (iii) 3,887,680 shares subject to outstanding 2013, 2014 and 2015 performance units (including 145,581 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, 2015, employing the fungible share formula and presumes the issuance of target shares under the performance units granted in 2013, 2014 and 2015 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.

(2) This plan has terminated as to future grants. The number under column (a) with respect to this plan includes 26,619 shares issuable upon the vesting of outstanding RSUs (including 3,256 related dividend equivalents), which are not included in calculating the weighted average exercise price in column (b).

(3) This plan has terminated as to future grants. This plan was originally assumed pursuant to the terms of the merger agreement between Amgen and Immunex which was approved by our stockholders in May 2002. This plan was previously approved by Immunex's shareholders.

(4) This plan has terminated as to future grants. This plan was originally assumed by Amgen in connection with the merger of Abgenix with and into Amgen Fremont Inc., a wholly owned subsidiary of Amgen, on April 1, 2006. The number under column (a) with respect to this plan includes 57 shares issuable upon the vesting of outstanding RSUs, which are not included in calculating the weighted average exercise price in column (b).

(5) This plan has terminated as to future grants. This plan was originally assumed by Amgen in connection with the merger of Avidia, Inc. with and into Amgen Mountain View Inc., a wholly owned subsidiary of Amgen, on October 24, 2006.

(6) 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 AND 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 March 6, 2013). (Filed as an exhibit to Form 8-K on March 6, 2013 and incorporated herein by reference.)
3.3	First Amendment to the Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated March 6, 2013). (Filed as an exhibit to Form 8-K on October 16, 2013 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.)

Exhibit No.	Description
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.)
4.1	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.)
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.)

Exhibit No.	Description
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+	Form of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on 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.)
10.4+	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on October 14, 2015.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2015 on November 2, 2015 and incorporated herein by reference.)
10.5+	Amgen Inc. 2009 Performance Award Program. (As Amended on December 13, 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.)
10.6+	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on October 14, 2015.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2015 on November 2, 2015 and incorporated herein by reference.)
10.7+	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on 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.)
10.8+	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.)
10.9+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on 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.)
10.10+	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.)
10.11+	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.)
10.12+	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.)
10.13+	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.)

10.14+	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.)
10.15+	Agreement between Amgen Inc. and David W. Meline, effective July 21, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2014 on October 29, 2014 and incorporated herein by reference.)
10.16+	Agreement between Amgen Inc. and Jonathan Graham, dated May 11, 2015. (Filed as an exhibit to Form 10-Q/A for the quarter ended June 30, 2015 on August 6, 2015 and incorporated herein by reference.)
10.17	Shareholders' Agreement, dated May 11, 1984, among Amgen, Kirin Brewery Company, Limited and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.18	Amendment No. 1 dated March 19, 1985, Amendment No. 2 dated July 29, 1985 (effective July 1, 1985), and Amendment No. 3, dated December 19, 1985, to the Shareholders' Agreement dated May 11, 1984. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)

Exhibit No.	Description
10.19	Amendment No. 4 dated October 16, 1986 (effective July 1, 1986), Amendment No. 5 dated December 6, 1986 (effective July 1, 1986), Amendment No. 6 dated June 1, 1987, Amendment No. 7 dated July 17, 1987 (effective April 1, 1987), Amendment No. 8 dated May 28, 1993 (effective November 13, 1990), Amendment No. 9 dated December 9, 1994 (effective June 14, 1994), Amendment No. 10 effective March 1, 1996, and Amendment No. 11 effective March 20, 2000 to the Shareholders' Agreement, dated May 11, 1984. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.20	Amendment No. 12 to the Shareholders' Agreement, dated January 31, 2001. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2005 on August 8, 2005 and incorporated herein by reference.)
10.21	Amendment No. 13 to the Shareholders' Agreement, dated June 28, 2007 (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.22	Amendment No. 14 to the Shareholders' Agreement, dated March 26, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2014 on April 30, 2014 and incorporated herein by reference.)
10.23	Assignment and License Agreement, dated October 16, 1986 (effective July 1, 1986), between Amgen and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.24	G-CSF United States License Agreement, dated June 1, 1987 (effective July 1, 1986), Amendment No. 1, dated October 20, 1988, and Amendment No. 2, dated October 17, 1991 (effective November 13, 1990), between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.25	G-CSF European License Agreement, dated December 30, 1986, between Kirin-Amgen and Amgen, Amendment No. 1 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated June 1, 1987, Amendment No. 2 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated March 15, 1998, Amendment No. 3 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated October 20, 1988, and Amendment No. 4 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated December 29, 1989, between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.26	Amended and Restated Promotion Agreement, dated December 16, 2001, by and among Immunex Corporation, American Home Products Corporation and Amgen Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Amendment No. 1 to Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
10.27	Description of Amendment No. 1 to Amended and Restated Promotion Agreement, effective July 8, 2003, among Wyeth, Amgen Inc. and Immunex Corporation (portions of the exhibit have been

	omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2003 on March 11, 2004 and incorporated herein by reference.)
10.28	Description of Amendment No. 2 to Amended and Restated Promotion Agreement, effective April 20, 2004, by and among Wyeth, Amgen Inc. and Immunex Corporation. (Filed as an exhibit to Amendment No. 1 to Form S-4 Registration Statement on June 29, 2004 and incorporated herein by reference.)
10.29	Amendment No. 3 to Amended and Restated Promotion Agreement, effective January 1, 2005, by and among Wyeth, Amgen Inc. and Immunex Corporation (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2005 on May 4, 2005 and incorporated herein by reference.)
10.30	Amended and Restated Credit Agreement, dated July 30, 2014, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent (Filed as an exhibit to Form 8-K on July 30, 2014 and incorporated herein by reference.)
10.31	Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)

Exhibit No.	Description
10.32	Sourcing and Supply Agreement, dated November 15, 2011, by and between Amgen USA Inc, a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 on February 29, 2012 and incorporated herein by reference.)
10.33	Amendment Number 1 to Sourcing and Supply Agreement, effective January 1, 2013, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Healthcare Partners Inc. f/k/a DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.)
10.34	Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)
10.35	Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.36	Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.37	Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.38	Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.39	Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
10.40	Term Loan Facility Credit Agreement, dated September 20, 2013, among Amgen Inc., the Banks therein named, Bank of America, N.A., as Administrative Agent, and Barclays Bank PLC and JPMorgan Chase Bank, N.A., as Syndication Agents. (Filed as an exhibit to Form 8-K on September 20, 2013 and incorporated herein by reference.)
21*	Subsidiaries of the Company.
23	

	Consent of the Independent Registered Public Accounting Firm. The consent is set forth on page 69 of this Annual Report on Form 10-K.
24	Power of Attorney. The Power of Attorney is set forth on page 70 of this Annual Report on Form 10-K.
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

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

SIGNATURES

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

AMGEN INC.
(Registrant)

Date: February 16, 2016

By: /S/ DAVID W. MELINE
David W. Meline
Executive Vice President and Chief Financial Officer

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

- Registration Statement (Form S-8 No. 333-159377) pertaining to the Amgen Inc. 2009 Equity Incentive Plan;
- Registration Statement (Form S-8 No. 33-39183) pertaining to the Amended and Restated Employee Stock Purchase Plan;
- Registration Statements (Form S-8 No. 33-39104, as amended by Form S-8 No. 333-144581) pertaining to the Amended and Restated Amgen Retirement and Savings Plan (formerly known as the Amgen Retirement and Savings Plan);
- Registration Statements (Form S-8 Nos. 33-42072 and 333-144579) pertaining to the Amgen Inc. Amended and Restated 1991 Equity Incentive Plan;
- Registration Statements (Form S-8 Nos. 33-47605 and 333-144580) pertaining to the Retirement and Savings Plan for Amgen Manufacturing, Limited (formerly known as the Retirement and Savings Plan for Amgen Manufacturing, Inc.);
- Registration Statements (Form S-8 Nos. 333-81284 and 333-177868) pertaining to the Amgen Nonqualified Deferred Compensation Plan;
- Registration Statements (Form S-8 No. 333-92424 and Amendment No. 1 thereto) pertaining to the Amgen Inc. Amended and Restated 1999 Equity Incentive Plan (formerly known as the Immunex Corporation 1999 Stock Option Plan);
- Registration Statements (Form S-8 Nos. 333-132932 and 333-133002) pertaining to the Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (formerly known as Abgenix, Inc. 1999 Nonstatutory Stock Option Plan, as amended and restated);
- Registration Statement (Form S-8 No. 333-138325) pertaining to the Amgen Inc. Amended and Restated Assumed Avidia Equity Incentive Plan (formerly known as the Avidia, Inc. Amended and Restated 2003 Equity Incentive Plan);
- Registration Statement (Form S-3 No. 333-194103) relating to debt securities, common stock, preferred stock, warrants to purchase debt securities, common stock, preferred stock or depositary shares, rights to purchase common stock or preferred stock, securities purchase contracts, securities purchase units and depositary shares of Amgen Inc. and in the related Prospectus; and
- Registration Statement (Form S-8 No. 333-176240) pertaining to the Amgen Profit Sharing Plan for Employees in Ireland;

of our reports dated February 16, 2016, with respect to the consolidated financial statements and schedule of Amgen Inc. and the effectiveness of internal control over financial reporting of Amgen Inc. included in this Annual Report (Form 10-K) of Amgen Inc. for the year ended December 31, 2015.

/s/ Ernst & Young LLP

Los Angeles, California

February 16, 2016

EXHIBIT 24
POWER OF ATTORNEY
KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David W. Meline, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming that said attorney-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.
Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/S/ ROBERT A. BRADWAY Robert A. Bradway	Chairman of the Board, Chief Executive Officer and President, and Director (Principal Executive Officer)	2/16/2016
/S/ DAVID W. MELINE David W. Meline	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	2/16/2016
/S/ ANNETTE SUCH Annette Such	Chief Accounting Officer (Principal Accounting Officer)	2/16/2016
/S/ DAVID BALTIMORE David Baltimore	Director	2/16/2016
/S/ FRANK J. BIONDI, JR. Frank J. Biondi, Jr.	Director	2/16/2016
/S/ FRANÇOIS DE CARBONNEL François de Carbonnel	Director	2/16/2016
/S/ VANCE D. COFFMAN Vance D. Coffman	Director	2/16/2016
/S/ ROBERT A. ECKERT Robert A. Eckert	Director	2/16/2016
/S/ GREG C. GARLAND Greg C. Garland	Director	2/16/2016
/S/ FRED HASSAN Fred Hassan	Director	2/16/2016
/S/ REBECCA M. HENDERSON Rebecca M. Henderson	Director	2/16/2016
/S/ FRANK C. HERRINGER Frank C. Herringer	Director	2/16/2016

/S/ TYLER JACKS Tyler Jacks	Director	2/16/2016
/S/ JUDITH C. PELHAM Judith C. Pelham	Director	2/16/2016
/S/ RONALD D. SUGAR Ronald D. Sugar	Director	2/16/2016
/S/ R. SANDERS WILLIAMS R. Sanders Williams	Director	2/16/2016

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Amgen Inc.

We have audited the accompanying Consolidated Balance Sheets of Amgen Inc. (the "Company") as of December 31, 2015 and 2014, and 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, 2015. Our audits also included the financial statement schedule listed in the Index at Item 15(a) 2. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Amgen Inc. at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Amgen Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 16, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California

February 16, 2016

AMGEN INC.
CONSOLIDATED STATEMENTS OF INCOME
Years ended December 31, 2015, 2014 and 2013
(In millions, except per share data)

	2015	2014	2013
Revenues:			
Product sales	$20,944	$19,327	$18,192
Other revenues	718	736	484
Total revenues	21,662	20,063	18,676
Operating expenses:			
Cost of sales	4,227	4,422	3,346
Research and development	4,070	4,297	4,083
Selling, general and administrative	4,846	4,699	5,184
Other	49	454	196
Total operating expenses	13,192	13,872	12,809
Operating income	8,470	6,191	5,867
Interest expense, net	1,095	1,071	1,022
Interest and other income, net	603	465	420
Income before income taxes	7,978	5,585	5,265
Provision for income taxes	1,039	427	184
Net income	$6,939	$5,158	$5,081
Earnings per share:			
Basic	$9.15	$6.80	$6.75
Diluted	$9.06	$6.70	$6.64
Shares used in the calculation of earnings per share:			
Basic	758	759	753
Diluted	766	770	765

See accompanying notes.

AMGEN INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
Years ended December 31, 2015, 2014 and 2013
(In millions)

	2015	2014	2013
Net income	$6,939	$5,158	$5,081
Other comprehensive (loss) income, net of reclassification adjustments and taxes:			
Foreign currency translation losses	(247)	(196)	(80)
Effective portion of cash flow hedges	7	323	2
Net unrealized (losses) gains on available-for-sale securities	(241)	24	(226)
Other	9	2	(3)
Other comprehensive (loss) income, net of tax	(472)	153	(307)
Comprehensive income	$6,467	$5,311	$4,774

See accompanying notes.

AMGEN INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2015 and 2014
(In millions, except per share data)

	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$4,144	$3,731
Marketable securities	27,238	23,295
Trade receivables, net	2,995	2,546
Inventories	2,435	2,647
Other current assets	1,706	2,494
Total current assets	38,518	34,713
Property, plant and equipment, net	4,907	5,223
Intangible assets, net	11,641	12,693
Goodwill	14,787	14,788
Other assets	1,723	1,592
Total assets	$71,576	$69,009
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$965	$995
Accrued liabilities	5,452	5,513
Current portion of long-term debt	2,250	500
Total current liabilities	8,667	7,008
Long-term debt	29,306	30,215
Long-term deferred tax liability	2,239	3,461
Other noncurrent liabilities	3,281	2,547
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding — 754.0 shares in 2015 and 760.4 shares in 2014	30,649	30,410
Accumulated deficit	(2,086)	(4,624)
Accumulated other comprehensive loss	(480)	(8)
Total stockholders' equity	28,083	25,778
Total liabilities and stockholders' equity	$71,576	$69,009

See accompanying notes.

AMGEN INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years ended December 31, 2015, 2014 and 2013
(In millions)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total
Balance at December 31, 2012	756.3	$29,337	$(10,423)	$ 146	$19,060
Net income	—	—	5,081	—	5,081
Other comprehensive loss, net of tax	—	—	—	(307)	(307)
Dividends	—	—	(1,521)	—	(1,521)
Issuance of common stock in connection with the Company's equity award programs	7.4	296	—	—	296
Stock-based compensation	—	400	—	—	400
Settlement of conversion value of convertible debt in excess of principal	—	(99)	—	—	(99)
Settlement of convertible note hedge	—	99	—	—	99
Settlement of warrants	—	(100)	—	—	(100)
Tax impact related to employee stock-based compensation	—	(42)	—	—	(42)
Repurchases of common stock	(9.1)	—	(771)	—	(771)
Balance at December 31, 2013	754.6	29,891	(7,634)	(161)	22,096
Net income	—	—	5,158	—	5,158
Other comprehensive income, net of tax	—	—	—	153	153
Dividends	—	—	(1,995)	—	(1,995)
Issuance of common stock in connection with the Company's equity award programs	6.7	186	—	—	186
Stock-based compensation	—	404	—	—	404
Tax impact related to employee stock-based compensation	—	(71)	—	—	(71)
Repurchases of common stock	(0.9)	—	(153)	—	(153)
Balance at December 31, 2014	760.4	30,410	(4,624)	(8)	25,778
Net income	—	—	6,939	—	6,939
Other comprehensive loss, net of tax	—	—	—	(472)	(472)
Dividends	—	—	(2,548)	—	(2,548)
Issuance of common stock in connection with the Company's equity award programs	5.6	82	—	—	82
Stock-based compensation	—	319	—	—	319
Tax impact related to employee stock-based compensation	—	(162)	—	—	(162)
Repurchases of common stock	(12.0)	—	(1,853)	—	(1,853)
Balance at December 31, 2015	754.0	$30,649	$(2,086)	$ (480)	$28,083

See accompanying notes.

AMGEN INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2015, 2014 and 2013
(In millions)

	2015	2014	2013
Cash flows from operating activities:			
Net income	$6,939	$5,158	$5,081
Depreciation and amortization	2,108	2,092	1,286
Stock-based compensation expense	322	408	403
Deferred income taxes	(607)	(108)	(189)
Other items, net	(399)	(116)	103
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	(420)	136	(38)
Inventories	481	327	(7)
Other assets	155	(1)	(59)
Accounts payable	(12)	228	60
Accrued income taxes	509	(103)	(326)
Other liabilities	1	534	(23)
Net cash provided by operating activities	9,077	8,555	6,291
Cash flows from investing activities:			
Purchases of property, plant and equipment	(594)	(718)	(693)
Cash paid for acquisitions, net of cash acquired	(359)	(165)	(9,434)
Purchases of intangible assets	(55)	(285)	—
Purchases of marketable securities	(25,977)	(25,878)	(21,965)
Proceeds from sales of marketable securities	18,029	16,697	19,123
Proceeds from maturities of marketable securities	3,527	4,199	5,090
Proceeds from sale of property, plant and equipment	274	3	20
Change in restricted investments, net	—	533	(520)
Other	(392)	(138)	(90)
Net cash used in investing activities	(5,547)	(5,752)	(8,469)
Cash flows from financing activities:			
Net proceeds from issuance of debt	3,465	4,476	8,054
Repayment of debt	(2,400)	(5,605)	(3,371)
Repurchases of common stock	(1,867)	(138)	(832)
Dividends paid	(2,396)	(1,851)	(1,415)
Net proceeds from issuance of common stock in connection with the Company’s equity award programs	82	186	296
Settlement of contingent consideration obligations	(253)	(92)	—
Other	252	147	(6)
Net cash (used in) provided by financing activities	(3,117)	(2,877)	2,726
Increase (decrease) in cash and cash equivalents	413	(74)	548
Cash and cash equivalents at beginning of period	3,731	3,805	3,257
Cash and cash equivalents at end of period	$4,144	$3,731	$3,805

See accompanying notes.

AMGEN INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2015

1. Summary of significant accounting policies

Business

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

Principles of consolidation

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

Use of estimates

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

Product sales

Sales of our products are recognized when shipped and title and risk of loss have passed. Product sales are recorded net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively "sales deductions") and returns. Taxes collected from customers and remitted to government authorities related to the sales of the Company's products, primarily in Europe, are excluded from revenues.

We recognized revenue from the sale of product to the U.S. federal government for stockpile in accordance with U.S. Securities and Exchange Commission (SEC) Interpretation, Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile (SNS). We recognized $155 million of revenue for NEUPOGEN® during the year ended December 31, 2013, for purchases by the federal government for the SNS. There were no purchases by the federal government for the SNS during the years ended December 31, 2015 and 2014. We are contracted to manage this inventory of product until the federal government requests shipment.

Other revenues

Other revenues consist primarily of royalty income and corporate partner revenues. Royalties from licensees are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectability is reasonably assured. Royalty estimates are made in advance of amounts collected using historical and forecasted trends. Corporate partner revenues are comprised mainly of amounts earned from Kirin-Amgen, Inc. (K-A) and other third parties for certain research and development (R&D) services, which are recognized as the R&D services are performed, as well as our share of the U.S. pre-tax Nexavar® commercial profits that were generated from our collaboration with Bayer HealthCare Pharmaceuticals, Inc. (Bayer). Corporate partner revenues also include license fees and milestone payments earned from K-A and from other third parties. See Multiple-deliverable revenue arrangements, discussed below, Note 7, Collaborative arrangements, and Note 8, Related party transactions.

Multiple-deliverable revenue arrangements

From time to time, we enter into arrangements for the R&D, manufacture and/or commercialization of products and product candidates. These arrangements may require us to deliver various rights, services and/or goods across the entire life cycle of a product or product candidate, including (i) intellectual property rights/licenses, (ii) R&D services, (iii) manufacturing services and/or (iv) commercialization services. The underlying terms of these arrangements generally provide for consideration to Amgen in the form of non-refundable upfront license payments, R&D and commercial performance milestone payments, cost sharing and/or royalty payments.

In arrangements involving the delivery of more than one element, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. For Amgen, this determination is generally based on whether the deliverable has “stand-alone value” to the customer. The arrangement’s consideration that is fixed and determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price and (iii) best estimate of selling price (BESP). The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Consideration associated with at-risk substantive performance milestones is recognized as revenue upon the achievement of the related milestone, as defined in the respective contracts.

Research and development costs

R&D costs are expensed as incurred and include primarily salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems’ costs and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs and cost recoveries associated with third-party R&D arrangements such as with K-A, including upfront fees and milestones paid to third parties in connection with technologies which had not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 7, Collaborative arrangements, and Note 8, Related party transactions.

Selling, general and administrative costs

Selling, general and administrative (SG&A) costs are comprised primarily of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses; the U.S. healthcare reform federal excise fee on Branded Prescription Pharmaceutical Manufacturers and Importers; and other general and administrative costs. Advertising costs are expensed as incurred. SG&A expenses also include costs and cost recoveries associated with marketing and promotion efforts under certain collaboration arrangements. Net payment or reimbursement of SG&A costs is recognized when the obligations are incurred or we become entitled to the cost recovery. See Note 7, Collaborative arrangements.

Stock-based compensation

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

Income taxes

We provide for income taxes based on pretax income and applicable tax rates available in the various jurisdictions in which we operate. Deferred income taxes are recorded for the expected tax consequences of temporary differences between the bases of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. We record a valuation allowance to reduce our deferred tax assets to the amount of future tax benefit that is more likely than not to be realized.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits (UTBs) is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense. See Note 5, Income

taxes.

Business combinations

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method, assets acquired, including in-process research and development (IPR&D) projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection

with a business combination (including the assumption of an acquiree's liability arising from a business combination it consummated prior to our acquisition) are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in earnings. See Note 3, Business combinations, and Note 16, Fair value measurement.

Cash equivalents

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

Available-for-sale investments

We consider our investment portfolio available-for-sale and, accordingly, these investments are recorded at fair value with unrealized gains and losses generally recorded in other comprehensive income. Investments with maturities beyond one year, other than Restricted investments, may be classified as short-term marketable securities in the Consolidated Balance Sheets due to their highly liquid nature and because they represent the Company's investments that are available for current operations. See Note 9, Available-for-sale investments, and Note 16, Fair value measurement.

Inventories

Inventories are stated at the lower of cost or market. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner that approximates the first-in, first-out method. See Note 10, Inventories.

Derivatives

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Consolidated Balance Sheets. The accounting for changes in the fair value of a derivative instrument depends upon whether the derivative has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of hedging relationship. For derivatives formally designated as hedges, we assess both at inception and quarterly thereafter, whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item. Our derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings. See Note 16, Fair value measurement, and Note 17, Derivative instruments.

Property, plant and equipment, net

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

Goodwill and other intangible assets

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

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

significant delays in obtaining marketing

approval, the inability to bring a product to market and the introduction or advancement of competitors' products could result in partial or full impairment of the related intangible assets.

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

Restricted investments

From September 2013 to May 2014, we had restricted investments on our Consolidated Balance Sheet that were owned by ATL Holdings Limited (ATL Holdings), a wholly-owned subsidiary. ATL Holdings is an entity distinct from the Company and its other subsidiaries, with separate assets and liabilities. Because certain third parties owned Class A preferred shares of ATL Holdings, this entity was required to hold restricted investments, which were composed of interest-bearing securities, cash and related interest receivable. On May 22, 2014, the Company repurchased all of the outstanding Class A preferred shares, and therefore, we subsequently ceased to have restricted investments on our Consolidated Balance Sheet. See Note 14, Financing arrangements.

Contingencies

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

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.

Foreign currency translation

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

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The new standard, as amended, is effective for interim and annual periods beginning January 1, 2018, and may be adopted earlier, but not before January 1, 2017. The new standard is required to be adopted using either a full retrospective or a modified retrospective approach. We are currently evaluating the impact that this new standard will have on our consolidated financial statements.

In April 2015, the FASB issued a new accounting standard that amends the presentation for debt issuance costs. Upon adoption of the standard, such costs will be presented on our Consolidated Balance Sheet as a direct deduction from the carrying amount of the related debt liability and not as a deferred charge presented in Other assets on our Consolidated Balance Sheet. This new standard is effective for interim and annual periods beginning on January 1, 2016, and is required to be retrospectively adopted. We do not expect that adoption of this new standard will have a material impact on our consolidated financial statements.

In November 2015, the FASB issued a new accounting standard that amends the presentation of deferred income taxes on our Consolidated Balance Sheet such that they are presented entirely as noncurrent assets and liabilities. As permitted by the standard, we adopted the new presentation prospectively, beginning January 1, 2015. Consistent with our prospective adoption, presentation of deferred income tax assets and liabilities as of December 31, 2014, was not restated. If they had been restated, Other current assets and Long-term deferred tax liabilities would have been reduced by $660 million and $620 million, respectively, and Other noncurrent assets would have increased by $40 million.

In January 2016, the FASB issued a new accounting standard that amends the accounting and disclosures of financial instruments, including a provision that requires equity investments (except for investments accounted for under the equity method of accounting) to be measured at fair value with changes in fair value recognized in current earnings. The new standard is effective for interim and annual periods beginning on January 1, 2018. We are currently evaluating the impact that this new standard will have on our consolidated financial statements.

Reclassifications

Certain of our short-term obligations were reclassified from Accounts payable to Accrued liabilities on our Consolidated Balance Sheet at December 31, 2014, and related amounts within Net cash provided by operating activities in our Consolidated Statements of Cash Flows for the years ended December 31, 2014 and 2013, to conform to the current year presentation.

2. Restructuring and other cost savings initiatives

During the second half of 2014, we initiated a restructuring plan to invest in continuing innovation and the launch of our new pipeline molecules, while improving our cost structure. As part of the plan, we are closing our facilities in Washington state and Colorado and reducing the number of buildings we occupy at our headquarters in Thousand Oaks, California, as well as at other locations.

We estimate that we will incur $800 million to $900 million of pre-tax charges in connection with our restructuring plan, including: (i) separation and other headcount-related costs of $535 million to $585 million with respect to staff reductions, and (ii) asset-related charges of $265 million to $315 million consisting primarily of asset impairments, accelerated depreciation and other related costs resulting from the consolidation of our worldwide facilities. We incurred a total of $478 million of separation and other headcount-related costs and $194 million of net asset-related charges through December 31, 2015.

During the years ended December 31, 2015 and December 31, 2014, we incurred restructuring costs of $114 million and $558 million, respectively. We expect that we will incur most of the remaining estimated costs, as discussed above, in 2016 and 2017 in order to support our ongoing transformation and process improvement efforts.

The following table summarizes the charges recorded related to the restructuring plan by type of activity and the locations recognized within the Consolidated Statements of Income (in millions):

	During the year ended December 31, 2015				
	Separation Costs	Asset Impairments/Disposals	Accelerated Depreciation	Other	Total
Cost of sales	$—	$ —	$50	$2	$52
Research and development	—	—	36	28	64
Selling, general and administrative	—	—	14	42	56
Other	49	(111)	—	4	(58)
Total	$49	$ (111)	$100	$76	$114

	During the year ended December 31, 2014				
	Separation Costs	Asset Impairments	Accelerated Depreciation	Other	Total
Cost of sales	$—	$81	$23	$—	$104
Research and development	—	—	28	21	49
Selling, general and administrative	—	—	4	5	9
Other	377	6	—	13	396
Total	$377	$87	$55	$39	$558

We recognized asset impairment and accelerated depreciation charges in connection with our decision to exit Boulder and Longmont, Colorado, and Bothell and Seattle, Washington, and in connection with the consolidation of facilities in Thousand Oaks, California. The decision to close these manufacturing and R&D facilities was based principally on optimizing the utilization of our sites in the United States, which includes an expansion of our presence in the key U.S. biotechnology hubs of South San

Francisco, California, and Cambridge, Massachusetts. During the year ended December 31, 2015, we recognized gains from the sale of assets related to these site closures.

The following table summarizes the expenses (excluding non-cash charges) and payments related to the restructuring plan (in millions):

	During the year ended December 31, 2015		
	Separation Costs	Other	Total
Restructuring liabilities as of January 1, 2015	$221	$23	$244
Expense	52	80	132
Payments	(178)	(80)	(258)
Restructuring liabilities as of December 31, 2015	$95	$23	$118

	During the year ended December 31, 2014		
	Separation Costs	Other	Total
Restructuring liabilities as of January 1, 2014	$—	$—	$—
Expense	353	32	385
Payments	(132)	(9)	(141)
Restructuring liabilities as of December 31, 2014	$221	$23	$244

Other cost savings initiatives

In addition to, and separate from, the restructuring plan above, we incurred other charges as part of our efforts to achieve cost efficiencies in our operations. During the year ended December 31, 2013, we recorded certain charges aggregating approximately $71 million, which are included in Other operating expenses in the Consolidated Statement of Income. The expenses were primarily severance-related.

3. Business combinations

Dezima Pharma B.V.

On October 14, 2015, we acquired all of the outstanding stock of Dezima Pharma B.V. (Dezima), a privately-held, Netherlands-based biotechnology company focused on developing innovative treatments for dyslipidemia. Dezima's lead molecule is AMG 899 (formerly TA-8995), an oral, once-daily cholesteryl ester transfer protein inhibitor that has completed certain phase 2 trials. The rights to AMG 899 in certain territories in Asia, including Japan, are held by a third party. As part of the transaction, we assumed certain third-party agreements that were in place with Dezima to conduct R&D and manufacturing activities. The transaction, which was accounted for as a business combination, expands our cardiovascular portfolio. Upon its acquisition, Dezima became a wholly owned subsidiary of Amgen, and its operations have been included in our consolidated financial statements commencing on the acquisition date.

The aggregate acquisition date consideration to acquire Dezima consisted of (in millions):

Total cash paid to former shareholders of Dezima	$300
Fair value of contingent consideration obligations	110
Total consideration	$410

In connection with this acquisition, we are obligated to make additional payments to the former shareholders of Dezima of up to $1.25 billion contingent upon the achievement of certain development and sales-related milestones. In addition, low single-digit royalties will be paid on net product sales above a certain threshold. The estimated fair values of the contingent consideration obligations aggregated to $110 million as of the acquisition date and were determined using a combination of valuation techniques. See Note 16, Fair value measurement for information regarding the estimated fair values of these obligations as of December 31, 2015. The contingent consideration obligations relating to payments for regulatory milestones were valued based on assumptions regarding the probability of achieving the milestones and making the related payments, with such amounts discounted to present value based on our credit risk. The contingent consideration obligations relating to sales milestones were valued based on assumptions regarding the probability of achieving specified product sales thresholds to determine the required payments, with such amounts discounted to present value based on our credit risk.

The fair values of assets acquired and liabilities assumed primarily included IPR&D of $400 million, goodwill of $108 million and deferred tax liabilities of $100 million. This valuation reflects delayed development pending competitor clinical trials in this class. The estimated fair value of acquired IPR&D related to AMG 899 was determined using a probability-weighted income approach, which discounts expected future cash flows to present value using a discount rate that represents the estimated rate that market participants would use to value the assets. The projected cash flows were based on certain assumptions, including estimates of future revenues and expenses, the time and resources needed to complete development and the probabilities of obtaining marketing approval from regulatory agencies. The excess of the acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $108 million was recorded as goodwill, which is not deductible for tax purposes. Goodwill is attributable primarily to the expected synergies and other benefits that we believe will result from expanding our cardiovascular portfolio with AMG 899; and the deferred tax consequences of acquired IPR&D recorded for financial statement purposes.

The fair value estimates for the assets acquired and liabilities assumed were based upon preliminary calculations and valuations and our estimates and assumptions are subject to change as we obtain additional information during the measurement period (up to one year from the acquisition date). The primary areas of those preliminary estimates that are not yet finalized relate to IPR&D and tax related items.

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

Onyx Pharmaceuticals

On October 1, 2013, we acquired all of the outstanding stock of Onyx Pharmaceuticals, Inc. (Onyx), a global biopharmaceutical company engaged in the development and commercialization of innovative therapies for improving the lives of people afflicted with cancer. Onyx has a multiple myeloma franchise, with Kyprolis® already approved in the United States, and with oprozomib being evaluated in clinical trials for patients with hematologic malignancies. In addition, Onyx has three partnered oncology assets: Nexavar® tablets (an Onyx and Bayer compound), Stivarga® tablets (a Bayer compound) and Ibrance® (a Pfizer, Inc. (Pfizer) compound). This transaction, which was accounted for as a business combination, provides us with an opportunity to expand our oncology franchise. Onyx's operations have been included in our consolidated financial statements commencing on the acquisition date.

The aggregate acquisition date consideration to acquire Onyx was paid in cash and consisted of (in millions):

Total consideration transferred	$9,517
Compensation expense	197
Total consideration paid	$9,714

The $9,517 million cash payment consisted of a $9,186 million cash payment to the outstanding common stockholders and a $331 million cash payment to the Onyx equity award holders for services rendered prior to October 1, 2013 under the Onyx equity award plans. The remaining $197 million of cash, which related to the accelerated vesting of the remaining Onyx equity awards, was recognized as compensation expense during the three months ended December 31, 2013. This amount was included primarily in Selling, general and administrative expense in the Consolidated Statement of Income.

The consideration to acquire Onyx was allocated to the acquisition date fair values of assets acquired and liabilities assumed as follows (in millions):

Cash and cash equivalents	$319
Marketable securities	337
Inventories	170
Indefinite-lived intangible assets - IPR&D	1,180
Finite-lived intangible assets - Developed product technology rights	6,190
Finite-lived intangible assets - Licensing rights	2,792
Goodwill	2,402
Convertible debt	(742)
Assumed contingent consideration	(261)
Deferred income taxes, net	(3,011)
Other assets (liabilities), net	141
Total consideration (excluding compensation expense)	$9,517

The developed product technology rights acquired relate to Kyprolis® in the United States where it was approved at the acquisition date. This product technology is being amortized on a straight-line basis over the estimated useful life of 12 years.

Licensing rights acquired represent the aggregate estimated fair values of receiving future milestone, royalty and/or profit sharing payments associated with various contract agreements that were entered into by Onyx prior to the acquisition. The weighted-average useful life of these finite-lived intangible assets is ten years and they are being amortized on a straight-line basis.

The fair values of the developed product technology rights and licensing rights acquired were determined by estimating the probability-weighted net cash flows attributable to these rights discounted to present value using a discount rate that represents the estimated rate that market participants would use to value these intangible assets.

The estimated fair values of acquired IPR&D assets are related to the development of (i) Kyprolis® in territories outside the United States (excluding Japan), where regulatory approval to market the product had not been received at the acquisition date (see Note 12, Goodwill and intangible assets) and (ii) oprozomib. The estimated fair values at acquisition were determined using a probability-weighted income approach, which discounts expected future cash flows to present value using a discount rate that represents the estimated rate that market participants would use to value the assets. The projected cash flows from these projects were based on certain assumptions, including estimates of future revenues and expenses, the time and resources needed to complete development and the probabilities of obtaining marketing approval from regulatory agencies.

We assumed contingent consideration obligations upon the acquisition of Onyx arising from Onyx's 2009 acquisition of Proteolix, Inc. There were two separate milestone payments of $150 million each which were to be triggered if Kyprolis® received specified marketing approvals for relapsed multiple myeloma on or before March 31, 2016, by each of the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). The assumed contingent consideration value was determined by discounting probability-adjusted cash outflows to present value using a discount rate that represents the estimated rate that market participants would use. In December 2014, we renegotiated the terms of these milestones and settled the contingent consideration obligations with the former shareholders of Proteolix, Inc., by agreeing to make a single payment of $225 million, which was made during the first quarter of 2015.

The excess of the acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $2.4 billion was recorded as goodwill, which is not deductible for tax purposes and represents the future economic benefits arising from other assets acquired that could not be individually identified and separately recognized and the expected synergies and other benefits that we believe will result from combining the operations of Onyx with our operations.

We incurred $36 million of transaction-related expense which was recorded in Selling, general, and administrative expenses in the Consolidated Statement of Income for the year ended December 31, 2013.

Filgrastim and pegfilgrastim rights acquisition

In October 2013, we entered into an agreement to acquire the licenses to filgrastim and pegfilgrastim effective January 1, 2014 (acquisition date), that were held by F. Hoffmann-La Roche Ltd. (Roche) in approximately 100 markets in Eastern Europe, Latin America, Asia, the Middle East and Africa (Product Rights), and to settle our preexisting relationship related to the Product Rights for total consideration of $497 million. The acquisition of the Product Rights was accounted for as a business combination

as the acquired rights and processes are capable of producing an immediate return to us, and the settlement of the preexisting relationship was accounted for separately from the business combination. The operations of the acquired set of activities have been included in our consolidated financial statements commencing on the acquisition date.

The aggregate consideration transferred consisted of (in millions):

Total consideration transferred	$497
Settlement of preexisting relationship at fair value	(99)
Total consideration transferred to acquire the Product Rights	$398

The settlement of the preexisting relationship relates to a supply contract between Amgen and Roche that was terminated as a result of the acquisition of the Product Rights. The fair value of the contract of $99 million was recognized in Cost of sales in the Consolidated Statement of Income for the year ended December 31, 2014.

This transaction provides us with an opportunity to expand our geographic presence and reach more patients in more countries that could benefit from our therapies. The fair values of assets acquired and liabilities assumed primarily included marketing-related rights of $363 million, developed product technology rights of $11 million, goodwill of $3 million and other assets of $21 million. The marketing-related and developed product technology rights acquired relate to the Product Rights and are being amortized on a straight-line basis over their estimated useful lives of five years and three and one-half years, respectively.

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

For all IPR&D projects in the acquisitions discussed above, there are major risks and uncertainties associated with the timely and successful completion of development and commercialization of these product candidates, including our ability to confirm their safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not able to market a human therapeutic without obtaining regulatory approvals, and such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value, if any, of these acquired IPR&D projects may vary from their estimated fair values at the dates of acquisition.

4. Stock-based compensation

On May 22, 2013, our stockholders approved our Amended and Restated 2009 Equity Incentive Plan (the Amended 2009 Plan), which amended and restated our 2009 Equity Incentive Plan (the 2009 Plan) and increased the number of shares of our common stock authorized for issuance pursuant to equity-based awards under the 2009 Plan to approximately 104 million shares (plus any additional shares that are added back into the authorized pool as described below). Like the 2009 Plan, the Amended 2009 Plan provides for grants of equity-based awards, including RSUs, stock options and performance units to employees and consultants of Amgen, its subsidiaries and non-employee members of our Board of Directors. The 2009 Plan replaced our prior equity plans (the Prior Plans), and no further awards may be made under these Prior Plans. Consistent with the 2009 Plan, the pool of shares available under the Amended 2009 Plan is reduced by one share for each stock option granted and by 1.9 shares for other types of awards granted, including RSUs and performance units (full-value awards). Generally, if any shares subject to an award granted under the Amended 2009 Plan expire, or are forfeited, terminated or canceled without the issuance of shares, the shares subject to such awards are added back into the authorized pool on the same basis that they were removed. In addition, under the Amended 2009 Plan, shares withheld to pay for minimum statutory tax obligations with respect to full value awards are added back into the authorized pool on the basis of 1.9 shares. As of December 31, 2015, the Amended 2009 Plan provides for future grants and/or issuances of up to approximately 47 million shares of our common stock. Stock-based awards under our employee compensation plans are made with newly issued shares reserved for this purpose.

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

	Years ended December 31,		
	2015	2014	2013
RSUs	$190	$219	$206
Performance units	132	171	163
Stock options	—	18	34
Total stock-based compensation expense, pretax	322	408	403
Tax benefit from stock-based compensation expense	(120)	(152)	(149)
Total stock-based compensation expense, net of tax	$202	$256	$254

Restricted stock units and stock options

Eligible employees generally receive a grant of RSUs annually with the size and type of award generally determined by the employee's salary grade and performance level. In addition, certain management and professional level employees typically receive RSU grants upon commencement of employment. Our Board of Directors (outside directors) also receive an annual grant of RSUs. Prior to 2012, eligible employees also received a grant of stock options annually.

Our RSU grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including upon death, disability, a change in control, termination in connection with a change in control and the retirement of employees who meet certain service and/or age requirements. RSUs generally vest in approximately equal amounts on the second, third and fourth anniversaries of the grant date. RSUs granted on and after April 27, 2012, accrue dividend equivalents which are typically payable in shares only when and to the extent the underlying RSUs vest and are issued to the recipient. As of December 31, 2015, all outstanding stock options are vested.

Restricted stock units

The grant date fair value of an RSU equals the closing price of our common stock on the grant date as RSUs accrue dividend equivalents during their vesting period. The weighted-average grant date fair values of RSUs granted in 2015, 2014 and 2013 were $166.74, $115.63 and $107.01, respectively. The following summarizes select information regarding our RSUs:

	During the year ended December 31, 2015	
	Units (in millions)	Weighted-average grant date fair value
Balance nonvested at December 31, 2014	7.1	$92.88
Granted	1.4	$166.74
Vested	(2.7)	$76.85
Forfeited	(0.8)	$112.53
Balance nonvested at December 31, 2015	5.0	$118.89

The total fair values of shares associated with RSUs that vested during the years ended December 31, 2015, 2014 and 2013, were $206 million, $191 million and $145 million, respectively.

As of December 31, 2015, there were approximately $312 million of unrecognized compensation costs related to nonvested RSU awards, which are expected to be recognized over a weighted-average period of 1.7 years.

Stock options

The exercise price for stock options is set at the closing price of our common stock on the date of grant and the related number of shares granted is fixed at that point in time. Awards granted to employees on and after April 26, 2010, expire 10 years from the date of grant; options granted to employees prior to that date expire seven years from the date of grant. We did not grant stock options during the years ended December 31, 2015, 2014 and 2013.

The following summarizes select information regarding our stock options:

	During the year ended December 31, 2015			
	Options (in millions)	Weighted-average exercise price	Weighted-average remaining contractual life (years)	Aggregate intrinsic value (in millions)
Balance unexercised at December 31, 2014	4.1	$54.48		
Granted	—	$—		
Exercised	(1.3)	$50.99		
Expired/forfeited	—	$51.96		
Balance unexercised at December 31, 2015	2.8	$56.19	3.8	$294
Vested or expected to vest at December 31, 2015	2.8	$56.19	3.8	$294
Exercisable at December 31, 2015	2.8	$56.19	3.8	$294

The total intrinsic values of options exercised during the years ended December 31, 2015, 2014 and 2013, were $150 million, $228 million and $210 million, respectively. The actual tax benefits realized from tax deductions from option exercises during the three years ended December 31, 2015, 2014 and 2013, were $55 million, $83 million and $77 million, respectively.

Performance units

Certain management-level employees also receive annual grants of performance units, which give the recipient the right to receive common stock that is contingent upon achievement of specified pre-established goals over the performance period, which is generally three years. The performance goals for the units granted in 2015, 2014 and 2013, which are accounted for as equity awards, are based upon Amgen's stockholder return compared with a comparator group of companies, which are considered market conditions and are reflected in the grant date fair values of the units. The expense recognized for the awards is based on the grant date fair value of a unit multiplied by the number of units granted, net of estimated forfeitures. Depending on the outcome of these performance goals, a recipient may ultimately earn a number of units greater or less than the number of units granted. Shares of our common stock are issued on a one-for-one basis for each performance unit earned. In general, participants vest in their performance unit awards at the end of the performance period. The performance award program provides for accelerated or continued vesting in certain circumstances as defined in the plan, including upon death, disability, a change in control and retirement of employees who meet certain service and/or age requirements. Performance units accrue dividend equivalents which are typically payable in shares only when and to the extent the underlying performance units vest and are issued to the recipient, including with respect to market conditions that affect the number of performance units earned.

We used payout simulation models to estimate the grant date fair value of performance units granted in 2015, 2014 and 2013. The weighted-average assumptions used in these models and the resulting weighted-average grant date fair values of our performance units were as follows:

	Years ended December 31,		
	2015	2014	2013
Closing price of our common stock on grant date	$164.26	$112.43	$92.03
Volatility	24.3%	23.8%	21.0%
Risk-free interest rate	0.8%	0.8%	0.4%
Fair value of unit	$182.55	$104.47	$102.73

The payout simulation models also assumed correlations of returns of the stock prices of our common stock and the common stocks of the comparator groups of companies and stock price volatilities of the comparator groups of companies.

As of December 31, 2015 and 2014, a total of 3.8 million and 5.8 million performance units were outstanding with weighted-average grant date fair values of $121.34 and $92.66 per unit, respectively. During the year ended December 31, 2015, 0.9 million performance units with a weighted-average grant date fair value of $182.55 were

granted and 0.4 million performance units with a weighted-average grant date fair value of $112.28 were forfeited.

Because the performance period for performance units granted in 2013 began in January 2013 and ended in January 2016, no performance units vested during the year ended December 31, 2015. The total fair values of performance units that vested during 2014 and 2013 were $587 million and $270 million, respectively, based upon the number of performance units earned multiplied by the closing stock price of our common stock on the last day of the performance period.

As of December 31, 2015, there was approximately $113 million of unrecognized compensation cost related to the 2015 and 2014 performance unit grants that is expected to be recognized over a weighted-average period of approximately 1.0 years.

5. Income taxes

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

	Years ended December 31,		
	2015	2014	2013
Current provision:			
Federal	$1,129	$251	$54
State	40	58	26
Foreign	272	194	191
Total current provision	1,441	503	271
Deferred (benefit) provision:			
Federal	(290)	(22)	(86)
State	(78)	(4)	19
Foreign	(34)	(50)	(20)
Total deferred benefit	(402)	(76)	(87)
Total provision	$1,039	$427	$184

Deferred income taxes reflect the tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards and the tax effects of net operating loss (NOL) carryforwards.

Significant components of our deferred tax assets and liabilities were as follows (in millions):

	December 31,	
	2015	2014
Deferred income tax assets:		
NOL and credit carryforwards	$620	$588
Expense accruals	706	730
Expenses capitalized for tax	199	221
Stock-based compensation	179	206
Undistributed earnings of foreign subsidiaries	144	13
Other	161	178
Total deferred income tax assets	2,009	1,936
Valuation allowance	(327)	(336)
Net deferred income tax assets	1,682	1,600
Deferred income tax liabilities:		
Acquired intangibles	(3,633)	(4,089)
Other	(227)	(232)
Total deferred income tax liabilities	(3,860)	(4,321)
Total deferred income taxes, net	$(2,178)	$(2,721)

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

The valuation allowance for deferred tax assets decreased by $9 million and increased by $22 million in 2015 and 2014, respectively. The decrease in 2015 was due primarily to the release of valuation allowances against U.S. and foreign deferred tax assets due to the existence of sufficient taxable temporary differences that enable the use of the tax benefit of existing deferred tax assets. The increase in 2014 was due primarily to valuation allowances established as part of acquisitions and the Company's expectation that some state NOLs and R&D credits will not be utilized.

At December 31, 2015, we had $32 million of federal tax credit carryforwards available to reduce future federal income taxes and have provided no valuation allowance for those federal tax credit carryforwards. The federal tax credit carryforwards expire between 2026 and 2034. We had $330 million of state tax credit carryforwards available to reduce future state income taxes and have provided a valuation allowance for $241 million of those state tax credit carryforwards. All of the state tax credit carryforwards have no expiry.

At December 31, 2015, we had $132 million of NOL carryforwards available to reduce future federal income taxes and have provided a valuation allowance for $6 million of those federal NOL carryforwards. The federal NOL carryforwards, for which no valuation allowance has been provided, expire between 2020 and 2034. We had $580 million of NOL carryforwards available to reduce future state income taxes and have provided a valuation allowance for $499 million of those state NOL carryforwards. The state NOLs for which no valuation allowance has been provided expire between 2016 and 2035. We had $1.7 billion of NOL carryforwards available to reduce future foreign income taxes and have provided a valuation allowance for $750 million of those foreign NOL carryforwards. $241 million of the foreign NOLs for which no valuation allowance has been provided have no expiry; the remaining NOLs for which no valuation allowance has been provided will expire between 2016 and 2025.

The reconciliations of the total gross amounts of UTBs (excluding interest, penalties, foreign tax credits and the federal tax benefit of state taxes related to UTBs) were as follows (in millions):

	During the years ended December 31,		
	2015	2014	2013
Balance at beginning of year	$1,772	$1,415	$1,200
Additions based on tax positions related to the current year	413	379	335
Additions based on tax positions related to prior years	9	37	96
Reductions for tax positions of prior years	(32)	(45)	(192)
Reductions for expiration of statute of limitations	—	(12)	—
Settlements	(48)	(2)	(24)
Balance at end of year	$2,114	$1,772	$1,415

Substantially all of the UTBs as of December 31, 2015, if recognized, would affect our effective tax rate. During the year ended December 31, 2015, we settled various examinations with state tax authorities for prior tax years. During the year ended December 31, 2013, we settled our examination with the Internal Revenue Service (IRS) for the years ended December 31, 2007, 2008 and 2009. As a result of these developments, we remeasured our UTBs accordingly.

Interest and penalties related to UTBs are included in our provision for income taxes. During 2015, 2014 and 2013, we accrued approximately $17 million, $35 million and $32 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. At December 31, 2015 and 2014, accrued interest and penalties associated with UTBs totaled approximately $151 million and $134 million, respectively.

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

	Years ended December 31,		
	2015	2014	2013
Federal statutory tax rate	35.0 %	35.0 %	35.0 %
Foreign earnings, including earnings invested indefinitely	(18.1)%	(22.4)%	(21.3)%
Credits, Puerto Rico Excise Tax	(2.5)%	(4.4)%	(4.7)%
Credits, primarily federal R&D	(1.4)%	(1.5)%	(3.0)%
State taxes	0.1 %	0.7 %	0.8 %
Audit settlements (federal, state, foreign)	(0.5)%	— %	(3.7)%
Other, net	0.4 %	0.2 %	0.4 %
Effective tax rate	13.0 %	7.6 %	3.5 %

The effective tax rates for the years ended December 31, 2015, 2014 and 2013, are different from the federal statutory rates primarily as a result of indefinitely invested earnings of our foreign operations. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be invested indefinitely outside the United States. Substantially all of the benefit from foreign earnings on our effective tax rate results from foreign income associated with the Company's operation conducted in Puerto Rico that is subject to a tax incentive grant that expires in 2020. At December 31, 2015, the cumulative amount of these earnings was approximately $32.6 billion. If these earnings were repatriated to the United States, we would be required to accrue and pay approximately $11.4 billion of additional income taxes based on the current tax rates in effect.

Our total foreign income before income taxes was approximately $4.4 billion, $4.1 billion and $3.7 billion for the years ended December 31, 2015, 2014 and 2013, respectively.

Puerto Rico imposes an excise tax on the gross intercompany purchase price of goods and services from our manufacturer in Puerto Rico. The rate was 2.75% in the first half of 2013 and 4.0% effective July 1, 2013 through December 31, 2017. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in cost of sales when the related products are sold. For U.S. income tax purposes, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes when the excise tax is incurred.

Because the American Taxpayer Relief Act of 2012 was not enacted until 2013, certain provisions of the Act benefiting the Company's 2012 federal taxes, including the retroactive extension of the R&D tax credit for 2012, were not recognized in the Company's 2012 financial results and instead are reflected in the Company's 2013 financial results. The tax benefit of the retroactive extension of the 2012 R&D tax credit that was recognized in 2013 was $70 million.

Income taxes paid during the years ended December 31, 2015, 2014 and 2013, totaled $919 million, $269 million and $321 million, respectively.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely audited by the tax authorities in those jurisdictions. Significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions, the use of tax credits and allocations of income among various tax jurisdictions because of differing interpretations of tax laws and regulations. We are no longer subject to U.S. federal income tax examinations for tax years ended on or before December 31, 2009, or to California state income tax examinations for tax years ended on or before December 31, 2008. We are currently under audit by the IRS for tax years ended December 31, 2010, 2011 and 2012.

6. Earnings per share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which include principally shares that may be issued under: our stock option, restricted stock and performance unit awards, determined using the treasury stock method; and our convertible notes and warrants while outstanding (collectively "dilutive securities"). For further information regarding our convertible notes and warrants, see Note 14, Financing arrangements.

The computation for basic and diluted EPS was as follows (in millions, except per share data):

	Years ended December 31,		
	2015	2014	2013
Income (Numerator):			
Net income for basic and diluted EPS	$6,939	$5,158	$5,081
Shares (Denominator):			
Weighted-average shares for basic EPS	758	759	753
Effect of dilutive securities	8	11	12
Weighted-average shares for diluted EPS	766	770	765
Basic EPS	$9.15	$6.80	$6.75
Diluted EPS	$9.06	$6.70	$6.64

For each of the three years ended December 31, 2015, the number of anti-dilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

7. Collaborative arrangements

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

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for non-refundable upfront license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration agreements are performed with no guarantee of either technological or commercial success and each is unique in nature. Our significant arrangements are discussed below.

Pfizer Inc.

The co-promotion term of our Enbrel® collaboration agreement with Pfizer in the United States and Canada expired on October 31, 2013. Under the collaboration agreement in which we were the principal participant, Amgen and Pfizer shared in the agreed-upon selling and marketing expenses approved by a joint committee. We paid Pfizer a percentage of annual gross profits on our ENBREL sales in the United States and Canada on a scale that increased with gross profits; however, we maintained a majority share of ENBREL profits. Upon expiration of the co-promotion term, we are required to pay Pfizer residual royalties based on a declining percentage of annual net ENBREL sales in the United States and Canada for three years, ranging from 12% to 10%. The amounts of such payments are significantly less than what was owed based on the terms of the previous ENBREL profit share. Effective November 1, 2016, there will be no further royalty payments.

During the years ended December 31, 2015 and 2014, royalties due to Pfizer on ENBREL sales were $561 million and $509 million, respectively. During the year ended December 31, 2013, the aggregate net amount due to Pfizer for the ENBREL profit share and the royalties on ENBREL sales after the expiration of the co-promotion term, net of their share of selling and marketing expense was $1.3 billion. These amounts are included in Selling, general and administrative expense in the Consolidated Statements of Income.

Glaxo Group Limited

On April 1, 2014, we entered into a Termination and Transition Agreement which terminated our collaboration with Glaxo Group Limited (Glaxo), a wholly owned subsidiary of GlaxoSmithKline plc, for the commercialization of denosumab for osteoporosis indications for all countries and regions, except for Australia. In December 2015, we entered into an agreement to terminate the collaboration for Australia. Prior to termination, the collaboration included the European Union (EU), Switzerland, Australia, Norway, Russia and Mexico. We shared equally in the commercialization profits and losses related to the collaboration after accounting for expenses, including an amount payable to us in recognition of our discovery and development of denosumab. Glaxo was responsible for bearing a portion of the cost of certain specified development activities.

Amgen was the principal participant in the collaboration, and accordingly, we recorded product sales to third parties net of estimated returns, rebates and other deductions. During the years ended December 31, 2015 and 2014, product sales under the collaboration were not material and during the year ended December 31, 2013, product sales under the collaboration were $219 million. During the years end December 31, 2015, 2014 and 2013, net cost recoveries due to/from Glaxo under the collaboration agreement were not material.

AstraZeneca plc

We are in a collaboration with AstraZeneca plc (AstraZeneca) to jointly develop and commercialize certain antibodies from Amgen's clinical inflammation portfolio, including AMG 157, AMG 181, AMG 557 and AMG 570. The agreement covers the worldwide development and commercialization of these antibodies, except for AMG 557 and AMG 570 in Japan. AMG 139 and brodalumab were formerly part of the collaboration in certain territories. As of April 1, 2015, we have suspended our participation in the co-development and commercialization of AMG 139, with the option of resuming such participation at a later date. As of August 26, 2015, we terminated our participation in the co-development and commercialization of brodalumab. From and after termination, the clinical development and commercialization of brodalumab are at the sole discretion and expense of AstraZeneca. If AstraZeneca or its sublicensee commercialize brodalumab, Amgen would receive certain specified payments.

Under the terms of the agreement, approximately 65% of related development costs for the 2012-2014 periods were funded by AstraZeneca; beginning in 2015, the companies share costs equally. For each remaining collaboration product approved for sale, Amgen would receive a mid-single-digit royalty, after which the worldwide commercialization profits and losses related to such remaining collaboration products would be shared equally.

During the years ended December 31, 2015, 2014 and 2013, cost recoveries recognized for development costs, which included brodalumab and AMG 139, were $61 million, $110 million and $194 million, respectively, which were included in Research and development expense in the Consolidated Statements of Income.

The collaboration agreement will continue in effect unless terminated in accordance with its terms.

UCB

We are in a collaboration with UCB for the development and commercialization of romosozumab. Under the agreement, we received the rights to commercialize romosozumab for all indications in the United States, Canada, Mexico and Japan. UCB has the rights for all EU members at the time of first regulatory approval, Australia and New Zealand. Prior to commercialization, countries that have not been initially designated will be designated to Amgen or UCB in accordance with the terms of the agreement.

Generally, development costs are shared equally and we will share equally in the worldwide commercialization profits and losses related to the collaboration after accounting for expenses.

The collaboration agreement will continue in effect unless terminated earlier in accordance with its terms.

During the years ended December 31, 2015, 2014 and 2013, the net costs recovered from UCB were $60 million, $96 million, and $66 million, respectively, which are included in Research and development expense in the Consolidated Statements of Income.

Bayer HealthCare Pharmaceuticals Inc.

As part of the Onyx transaction, we acquired a collaboration with Bayer to jointly develop and commercialize Nexavar® (sorafenib) worldwide, except in Japan. The rights to develop and market Nexavar® in Japan are reserved to Bayer.

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

In May 2015, we and Bayer amended the terms of the agreement, which terminated the co-promotion agreement in the United States. The termination was effective as of June 30, 2015, and transferred all U.S. operational responsibilities to Bayer, including commercial and medical affairs activities. Prior to the termination of the co-promotion agreement, we co-promoted Nexavar® with Bayer and shared equally in the profits or losses in the United States. In lieu of this profit share, Bayer now pays Amgen a royalty on U.S. sales of Nexavar® at a percentage rate in the high 30s. Amgen will no longer contribute sales force personnel or medical liaisons to support Nexavar® in the United States. There are

no changes to the global research and development or non-U.S. profit share arrangements in the original agreement, as discussed below.

In all countries outside the United States, excluding Japan, Bayer manages all commercialization activities and incurs all of the sales and marketing expenditures and mutually agreed R&D expenses, for which we continue to reimburse Bayer for half. In these countries, we continue to receive 50% of net profits on sales of Nexavar® after deducting certain Bayer-related costs.

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

We do not expect that the amendment to the collaboration will have a material impact on our consolidated results of operations. Prior to the amendment, Amgen was acting as an agent under the agreement and as such, revenue was derived by calculating net sales of Nexavar® to third-party customers and deducting the cost of goods sold, distribution costs, marketing costs, phase 4 clinical trial costs, allocable overhead costs and certain other costs. Prior to the termination of the co-promotion during the years ended December 31, 2015 and 2014, and during the three months ended December 31, 2013, Amgen recorded Nexavar® net profits of $257 million, $324 million and $78 million, respectively, which were recognized as Other revenues in the Consolidated Statements of Income. Pursuant to the May 2015 amendment to the agreement, Amgen recorded royalty income subsequent to the termination of the co-promotion of $72 million on the U.S. sales of Nexavar® in Other revenues in the Consolidated Statement of Income. In addition, during the years ended December 31, 2015 and 2014, and the three months ended December 31, 2013, net R&D expenses related to the agreement were not material.

Other

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

8. Related party transactions

We own a 50% interest in K-A, a corporation formed in 1984 with Kirin Holdings Company, Limited (Kirin) for the development and commercialization of certain products based on advanced biotechnology. All of our rights to manufacture and market certain products including pegfilgrastim, granulocyte colony-stimulating factor, darbepoetin alfa, recombinant human erythropoietin and romiplostim are pursuant to exclusive licenses from K-A, which we currently market under the brand names Neulasta®, NEUPOGEN®/GRANULOKINE®, Aranesp®, EPOGEN®, and Nplate®, respectively.

We account for our interest in K-A using the equity method and include our share of K-A’s profits or losses in Selling, general and administrative expense in the Consolidated Statements of Income. For the years ended December 31, 2015, 2014 and 2013, our share of K-A’s profits and losses were profits of $65 million and $30 million and losses of $6 million, respectively. The carrying value of our equity method investment in K-A was approximately $443 million and $378 million as of December 31, 2015 and 2014, respectively, and is included in noncurrent Other assets in the Consolidated Balance Sheets.

K-A’s revenues consist of royalty income related to its licensed technology rights. K-A receives royalty income from us, as well as from Kirin and Johnson & Johnson under separate product license contracts for certain geographic areas outside the United States. During the years ended December 31, 2015, 2014 and 2013, K-A earned royalties from us of $264 million, $301 million and $272 million, respectively. These amounts are included in Cost of sales in the Consolidated Statements of Income.

K-A’s expenses consist primarily of costs related to R&D activities conducted on its behalf by Amgen and Kirin. K-A pays Amgen and Kirin for such services at negotiated rates. During the years ended December 31, 2015, 2014 and 2013, we earned revenues from K-A of $65 million, $119 million and $117 million, respectively, for certain R&D activities performed on K-A’s behalf. These amounts are recognized as Other revenues in the Consolidated Statements of Income. During the years ended December 31, 2015, 2014 and 2013, we recorded cost recoveries from K-A of $90 million, $108 million and $218 million, respectively, related to certain third-party costs. These amounts are included in Research and development expense in the Consolidated Statements of Income.

As of December 31, 2015 and 2014, we owed K-A $34 million and $17 million, respectively, which is included in Accrued liabilities respectively, in the Consolidated Balance Sheets.

9. Available-for-sale investments

The amortized cost, gross unrealized gains, gross unrealized losses and estimated fair values of available-for-sale investments by type of security were as follows (in millions):

Type of security as of December 31, 2015	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. Treasury securities	$4,298	$—	$(24)	$4,274
Other government-related debt securities:				
U.S.	536	—	(2)	534
Foreign and other	1,768	7	(36)	1,739
Corporate debt securities:				
Financial	7,904	7	(40)	7,871
Industrial	7,961	11	(136)	7,836
Other	905	1	(21)	885
Residential mortgage-backed securities	1,484	1	(15)	1,470
Other mortgage- and asset-backed securities	2,524	—	(55)	2,469
Money market mutual funds	3,370	—	—	3,370
Other short-term interest-bearing securities	528	—	—	528
Total interest-bearing securities	31,278	27	(329)	30,976
Equity securities	88	48	—	136
Total available-for-sale investments	$31,366	$75	$(329)	$31,112

Type of security as of December 31, 2014	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. Treasury securities	$3,632	$22	$(8)	$3,646
Other government-related debt securities:				
U.S.	530	1	(3)	528
Foreign and other	1,572	21	(24)	1,569
Corporate debt securities:				
Financial	6,036	21	(16)	6,041
Industrial	6,394	23	(66)	6,351
Other	650	3	(4)	649
Residential mortgage-backed securities	1,708	4	(10)	1,702
Other mortgage- and asset-backed securities	1,837	—	(41)	1,796
Money market mutual funds	3,004	—	—	3,004
Other short-term interest-bearing securities	1,302	—	—	1,302
Total interest-bearing securities	26,665	95	(172)	26,588
Equity securities	98	48	(2)	144
Total available-for-sale investments	$26,763	$143	$(174)	$26,732

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

	December 31,	
Classification in the Consolidated Balance Sheets	2015	2014
Cash and cash equivalents	$3,738	$3,293
Marketable securities	27,238	23,295
Other assets — noncurrent	136	144
Total available-for-sale investments	$31,112	$26,732

Cash and cash equivalents in the table above excludes cash of $406 million and $438 million as of December 31, 2015 and 2014, respectively.

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

	December 31,	
Contractual maturity	2015	2014
Maturing in one year or less	$4,578	$4,936
Maturing after one year through three years	9,370	6,829
Maturing after three years through five years	9,932	7,840
Maturing after five years through ten years	3,087	3,267
Maturing after ten years	70	218
Mortgage- and asset-backed securities	3,939	3,498
Total interest-bearing securities	$30,976	$26,588

For the years ended December 31, 2015, 2014 and 2013, realized gains totaled $132 million, $149 million and $158 million, respectively, and realized losses totaled $208 million, $150 million and $83 million, respectively. The cost of securities sold is based on the specific identification method.

The unrealized losses on available-for-sale investments and their related fair values were as follows (in millions):

	Less than 12 months		12 months or greater	
Type of security as of December 31, 2015	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	$4,196	$(24)	$—	$—
Other government-related debt securities:				
U.S.	494	(2)	20	—
Foreign and other	1,306	(32)	56	(4)
Corporate debt securities:				
Financial	5,988	(38)	228	(2)
Industrial	5,427	(108)	679	(28)
Other	807	(19)	39	(2)
Residential mortgage-backed securities	804	(8)	304	(7)
Other mortgage- and asset-backed securities	1,834	(19)	561	(36)
Total	$20,856	$(250)	$1,887	$(79)

Type of security as of December 31, 2014	Less than 12 months		12 months or greater	
	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	$1,770	$(7)	$171	$(1)
Other government-related debt securities:				
U.S.	160	—	178	(3)
Foreign and other	514	(14)	159	(10)
Corporate debt securities:				
Financial	3,150	(14)	158	(2)
Industrial	3,931	(62)	222	(4)
Other	354	(4)	5	—
Residential mortgage-backed securities	614	(4)	413	(6)
Other mortgage- and asset-backed securities	1,071	(8)	561	(33)
Equity securities	78	(2)	—	—
Total	$11,642	$(115)	$1,867	$(59)

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.

We review our available-for-sale investments for other-than-temporary declines in fair value below our cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. This evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below our cost basis and adverse conditions related specifically to the security, including any changes to the credit rating of the security, and the intent to sell, or whether we will more likely than not be required to sell, the security before recovery of its amortized cost basis. Our assessment of whether a security is other-than-temporarily impaired could change in the future due to new developments or changes in assumptions related to any particular security. As of December 31, 2015 and 2014, we believe the costs basis for our available-for-sale investments were recoverable in all material aspects.

10. Inventories

Inventories consisted of the following (in millions):

	December 31,	
	2015	2014
Raw materials	$201	$198
Work in process	1,529	1,551
Finished goods	705	898
Total inventories	$2,435	$2,647

11. Property, plant and equipment

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

	Useful life (in years)	December 31, 2015	2014
Land	—	$319	$398
Buildings and improvements	10-40	3,638	3,612
Manufacturing equipment	8-12	2,051	1,711
Laboratory equipment	8-12	1,140	1,240
Other	3-15	4,278	4,112
Construction in progress	—	746	1,183
Property, plant and equipment, gross		12,172	12,256
Less accumulated depreciation and amortization		(7,265)	(7,033)
Property, plant and equipment, net		$4,907	$5,223

During the years ended December 31, 2015, 2014 and 2013, we recognized depreciation and amortization charges associated with our property, plant and equipment of $727 million, $716 million and $644 million, respectively.

12. Goodwill and other intangible assets

Goodwill

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

	During the years ended December 31, 2015	2014
Beginning balance	$14,788	$14,968
Goodwill related to acquisitions of businesses [1]	108	(114)
Currency translation and other adjustments	(109)	(66)
Ending balance	$14,787	$14,788

[1] Consists of goodwill recognized on the acquisition dates of business combinations and subsequent adjustments to these amounts resulting from changes to the acquisition date fair values of net assets acquired in the business combinations recorded during their respective measurement periods.

Identifiable intangible assets

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

	December 31, 2015			2014		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
Finite-lived intangible assets:						
Developed product technology rights	$12,310	$(4,996)	$7,314	$10,826	$(4,155)	$6,671
Licensing rights	3,275	(998)	2,277	3,236	(696)	2,540
R&D technology rights	1,134	(635)	499	1,167	(569)	598
Marketing-related rights	1,186	(650)	536	1,241	(512)	729
Total finite-lived intangible assets	17,905	(7,279)	10,626	16,470	(5,932)	10,538
Indefinite-lived intangible assets:						
IPR&D	1,015	—	1,015	2,155	—	2,155
Total identifiable intangible assets	$18,920	$(7,279)	$11,641	$18,625	$(5,932)	$12,693

Developed product technology rights consist of rights related to marketed products acquired in business combinations. Licensing rights consist primarily of contractual rights acquired as part of the acquisition of Onyx to receive future milestones(see Note 3, Business combinations), royalties and profit sharing payments, capitalized payments to third parties for milestones related to regulatory approvals to commercialize products and upfront payments associated with royalty obligations for marketed products. R&D technology rights consist of technology used in R&D with alternative future uses. Marketing-related intangible assets consist primarily of rights related to the sale and distribution of marketed products, including licenses to filgrastim and pegfilgrastim acquired from Roche (see Note 3, Business combinations). Marketing-related intangible assets also includes $275 million paid to Glaxo during the year ended December 31, 2014, for the early termination of our agreement with them to commercialize denosumab in certain geographic areas (see Note 7, Collaborative arrangements). This transaction represents the reacquisition of a previously shared economic interest in geographic territories where we were already marketing denosumab and accordingly was accounted for as an acquisition of identifiable intangible assets.

IPR&D consists of R&D projects acquired in a business combination which are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of the required regulatory approvals. As of December 31, 2015, these projects include: AMG 899 acquired in the acquisition of Dezima (see Note 3, Business combinations), oprozomib acquired in the acquisition of Onyx (see Note 3, Business combinations), and Parsabiv™ (etelcalcetide) acquired in the acquisition of KAI Pharmaceuticals.

In October 2015, we announced that the FDA has granted approval of IMLYGIC™ (talimogene laherparepvec) acquired in the acquisition of BioVex Group, Inc. (BioVex), for the local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients with melanoma recurrent after initial surgery. As a result, the $675 million carrying value of IMLYGIC™ was reclassified from IPR&D to Developed product technology rights during the fourth quarter of 2015, and is being amortized over its estimated useful life.

In November 2015, we announced that the European Commission granted marketing authorization for Kyprolis® in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. As a result, the $850 million carrying value of Kyprolis® in the territories outside the United States (excluding Japan) was reclassified from IPR&D to Developed product technology rights during the fourth quarter of 2015, and is being amortized over its useful life.

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

During the years ended December 31, 2015, 2014 and 2013, we recognized amortization charges associated with our finite-lived intangible assets, included primarily in Cost of sales in the Consolidated Statements of Income, of $1.4 billion, $1.4 billion and $642 million, respectively. The total estimated amortization for each of the next five years for our intangible assets is $1.4 billion, $1.3 billion, $1.1 billion, $1.1 billion and $1.0 billion in 2016, 2017, 2018, 2019 and 2020, respectively.

13. Accrued liabilities

Accrued liabilities consisted of the following (in millions):

	December 31,	
	2015	2014
Sales deductions	$1,486	$1,379
Employee compensation and benefits	916	920

Dividends payable	754	601
Clinical development costs	491	445
Sales returns reserve	390	361
Other	1,415	1,807
Total accrued liabilities	$5,452	$5,513

14. Financing arrangements

The carrying values and the fixed contractual coupon rates of our long-term borrowings were as follows (in millions):

	December 31,	
	2015	2014
2.30% notes due 2016 (2.30% 2016 Notes)	$750	$749
2.50% notes due 2016 (2.50% 2016 Notes)	1,000	1,000
2.125% notes due 2017 (2.125% 2017 Notes)	1,249	1,249
Floating Rate Notes due 2017	600	600
1.25% notes due 2017 (1.25% 2017 Notes)	849	849
5.85% notes due 2017 (5.85% 2017 Notes)	1,100	1,100
6.15% notes due 2018 (6.15% 2018 Notes)	500	500
Term Loan due 2018	1,975	4,375
4.375% euro-denominated notes due 2018 (4.375% 2018 euro Notes)	598	668
5.70% notes due 2019 (5.70% 2019 Notes)	999	999
Floating Rate Notes due 2019	250	250
2.20% notes due 2019 (2.20% 2019 Notes)	1,398	1,398
2.125% euro-denominated notes due 2019 (2.125% 2019 euro Notes)	731	814
4.50% notes due 2020 (4.50% 2020 Notes)	300	300
2.125% notes due 2020 (2.125% 2020 Notes)	750	—
3.45% notes due 2020 (3.45% 2020 Notes)	898	898
4.10% notes due 2021 (4.10% 2021 Notes)	999	998
3.875% notes due 2021 (3.875% 2021 Notes)	1,747	1,747
2.70% notes due 2022 (2.70% 2022 Notes)	499	—
3.625% notes due 2022 (3.625% 2022 Notes)	748	747
3.625% notes due 2024 (3.625% 2024 Notes)	1,398	1,398
3.125% notes due 2025 (3.125% 2025 Notes)	995	—
5.50% pound-sterling-denominated notes due 2026 (5.50% 2026 pound sterling Notes)	696	735
4.00% pound-sterling-denominated notes due 2029 (4.00% 2029 pound sterling Notes)	1,018	1,076
6.375% notes due 2037 (6.375% 2037 Notes)	899	899
6.90% notes due 2038 (6.90% 2038 Notes)	499	499
6.40% notes due 2039 (6.40% 2039 Notes)	996	996
5.75% notes due 2040 (5.75% 2040 Notes)	697	697
4.95% notes due 2041 (4.95% 2041 Notes)	596	596
5.15% notes due 2041 (5.15% 2041 Notes)	2,234	2,233
5.65% notes due 2042 (5.65% 2042 Notes)	1,245	1,245
5.375% notes due 2043 (5.375% 2043 Notes)	1,000	1,000
4.40% notes due 2045 (4.40% 2045 Notes)	1,243	—
Other notes	100	100
Total debt	31,556	30,715
Less current portion	(2,250)	(500)
Total noncurrent debt	$29,306	$30,215

Debt repayments

During the year ended December 31, 2015, we repaid $2.4 billion of principal on our Term Loan Credit Facility (Term Loan). During the year ended December 31, 2014, we repaid $5.6 billion of debt, including the Master Repurchase Agreement (Repurchase Agreement), the 1.875% 2014 Notes, the 4.85% 2014 Notes, $500 million of principal on our Term Loan and $5 million of Other notes. During the year ended December 31, 2013, our 0.375% 2013 Convertible Notes matured/converted, and the $2.5 billion principal amount was settled in cash, and we also

repaid $742 million of convertible debt assumed in the acquisition of Onyx, $125 million of principal on our Term Loan and $4 million of Other notes.

Debt issuances

We issued debt and debt securities in various offerings during the three years ended December 31, 2015, including:

- In May 2015, we issued $3.5 billion aggregate principal amount of notes, consisting of the 2.125% 2020 Notes, the 2.70% 2022 Notes, the 3.125% 2025 Notes and the 4.40% 2045 Notes. The notes may be redeemed at any time at our option, in whole or in part, at the principal amount of the notes being redeemed plus accrued and unpaid interest and, except as discussed below, a make-whole amount, as defined. The 2.125% 2020 Notes, the 2.70% 2022 Notes, the 3.125% 2025 Notes and the 4.40% 2045 Notes may be redeemed without payment of a make-whole amount if they are redeemed on or after one, two, three and six months, respectively, prior to their maturity dates.
- In 2014, we issued $4.5 billion aggregate principal amount of notes, comprised of the Floating Rate Notes due 2017, the 1.25% 2017 Notes, the Floating Rate Notes due 2019, the 2.20% 2019 Notes and the 3.625% 2024 Notes. The Floating Rate Notes due in 2017 and 2019 bear interest equal to three-month London Interbank Offered Rates (LIBOR) plus 0.38% and three-month LIBOR plus 0.60%, respectively, and are not subject to redemption at our option. The fixed rate notes that were issued may be redeemed at any time at our option, in whole or in part, at the principal amount of the notes being redeemed plus accrued and unpaid interest and, except as discussed below, a make-whole amount, as defined. The 2.20% 2019 Notes and 3.625% 2024 Notes may be redeemed without payment of a make-whole amount if they are redeemed on or after one month and three months, respectively, prior to their maturity dates.
- In 2013, we issued $8.1 billion of debt in connection with the acquisition of Onyx, comprised of obligations under a Repurchase Agreement and a Term Loan.

Debt issuance costs incurred in connection with these debt issuances in 2015, 2014 and 2013 totaled $21 million, $18 million and $46 million, respectively. These debt issuance costs are being amortized over the respective lives of the debt, and the related charge is included in Interest expense, net, in the Consolidated Statements of Income.

All of our notes, other than our Floating Rate Notes and Other notes, may be redeemed at any time at our option, in whole or in part, at the principal amount of the notes being redeemed plus accrued interest and, except for specified time periods described above regarding certain of our notes issued in 2014 and 2015, a make-whole amount, as defined. In addition, except with respect to our Other notes, in the event of a change-in-control triggering event, as defined, we may be required to purchase for cash all or a portion of these notes at a price equal to 101% of the principal amount of the notes plus accrued interest.

Master Repurchase Agreement

We entered into a Repurchase Agreement pursuant to which Amgen sold preferred shares of one of its wholly-owned subsidiaries, ATL Holdings, on September 30, 2013, and become obligated to repurchase the preferred shares from the counterparties for the aggregate sale price of $3.1 billion no later than September 28, 2018. In May 2014, we repurchased the shares for the aggregate sale price. While outstanding, we were obligated to make payments to the counterparties based on the sale price of the preferred shares at a floating interest rate based on the LIBOR plus 1.1%. The obligation to repurchase the preferred shares was accounted for as Long-term debt on our Consolidated Balance Sheet.

Term Loan Credit Facility

On October 1, 2013, we borrowed $5.0 billion under a Term Loan which bears interest at a floating rate based on LIBOR plus additional interest, initially 1%, which can vary based on the credit ratings assigned to our long-term debt by Standard & Poor's Financial Services LLC (S&P) and Moody's Investor Service, Inc. (Moody's). A minimum of $125 million of the principal amount of the loan is to be repaid at the end of each quarter, with the balance due on October 1, 2018. The outstanding balance of this loan may be prepaid in whole or in part at any time without penalty. This credit facility includes the same financial covenant as our revolving credit facility with respect to our level of borrowings in relation to our equity, as defined.

Convertible Notes

In 2006, we issued $2.5 billion principal amount of 0.375% 2013 Convertible Notes at par. The conversion value was payable in: (i) cash equal to the lesser of the principal amount of the note or the conversion value, as defined, and (ii) cash, shares of our common stock, or a combination of cash and shares of our common stock, at our option, to the extent the conversion value exceeded the principal amount of the note (the excess conversion value). In February

2013, our 0.375% 2013 Convertible Notes matured/converted, and accordingly, the $2.5 billion principal amount was settled in cash. We also elected to pay the note holders who converted their notes $99 million of cash for the excess conversion value, as allowed by the original terms of the notes.

Concurrent with the issuance of the 0.375% 2013 Convertible Notes, we purchased a convertible note hedge. The convertible note hedge allowed us to receive shares of our common stock and/or cash from the counterparty to the transaction equal to the amounts of common stock and/or cash related to the excess conversion value that we would issue and/or pay to the holders of the

0.375% 2013 Convertible Notes upon conversion. As a result of the conversion of the 0.375% 2013 Convertible Notes, we received $99 million of cash from the counterparty to offset the corresponding amount paid to the note holders.

On May 1, 2013, warrants to acquire 32 million shares of our common stock at an exercise price of $104.80 originally sold in connection with the issuance of the 0.375% 2013 Convertible Notes were exercised resulting in a net cash payment of $100 million.

Because the convertible note hedges and warrants could have been settled at our option in cash or shares of our common stock, and these contracts met all of the applicable criteria for equity classification under the applicable accounting standards, the cost of the convertible note hedges, the net proceeds from the sale of the warrants and the settlement of these contracts were classified in Stockholders' equity in the Consolidated Balance Sheets. In addition, because both of these contracts are classified in Stockholders' equity and were indexed to our common stock, they were not accounted for as derivatives.

Because these convertible notes were cash settleable, their debt and equity components were bifurcated and accounted for separately. The discounted carrying value of the debt component resulting from the bifurcation was accreted back to the principal amount over the period the notes were outstanding. Interest expense recognized during the year ended December 31, 2013, prior to the maturity/conversion of the 0.375% 2013 Convertible Notes was not material. The carrying amount of the equity component of this debt remains at $829 million.

Other notes

Other notes include our notes due in 2097 with a carrying value of $100 million.

Interest rate swaps

To achieve a desired mix of fixed and floating interest rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the life of the respective note. These interest rate swap contracts qualified and are designated as fair value hedges. As of December 31, 2015 and 2014, we had $6.65 billion notional amount of interest rate swap contracts outstanding, The effective interest rates on these notes after giving effect to the related interest rate swap contracts and the related notional amounts of the contracts were as follows as of December 31, 2015 (dollar amounts in millions):

Notes	Effective interest rate	Notional amount
1.25% 2017 Notes	LIBOR + 0.4%	$850
2.20% 2019 Notes	LIBOR + 0.6%	1,400
3.45% 2020 Notes	LIBOR + 1.1%	900
4.10% 2021 Notes	LIBOR + 1.7%	1,000
3.875% 2021 Notes	LIBOR + 2.0%	1,750
3.625% 2022 Notes	LIBOR + 1.6%	750
		$6,650

Cross-currency swaps

In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. The terms of these contracts effectively convert the interest payments and principal repayment on our 2.125% 2019 euro Notes, 5.50% 2026 pound sterling Notes and 4.00% 2029 pound sterling Notes from euros/pounds sterling to U.S. dollars. These cross-currency swap contracts have been designated as cash flow hedges. For information regarding the terms of these contracts, see Note 17, Derivative instruments.

Shelf registration statements and other facilities

As of December 31, 2015, we have a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working capital needs. At December 31, 2015 and 2014, we had no amounts outstanding under our commercial paper program.

In July 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. This term may be extended for up to two

additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.1% based on our current credit rating. Generally, we

would be charged interest at LIBOR plus 0.9% for any amounts borrowed under this facility. As of December 31, 2015 and 2014, no amounts were outstanding under this facility.

In February 2014, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depository shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depository shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2017.

In 1997, we established a $400 million medium-term note program under which medium-term debt securities may be offered from time to time with terms to be determined at the time of issuance. As of December 31, 2015 and 2014, no securities were outstanding under this medium-term note program.

Certain of our financing arrangements contain non-financial covenants. In addition, our revolving credit agreement and Term Loan each include a financial covenant with respect to the level of our borrowings in relation to our equity, as defined. We were in compliance with all applicable covenants under these arrangements as of December 31, 2015.

Contractual maturities of long-term debt obligations

The aggregate contractual maturities of all long-term debt obligations due subsequent to December 31, 2015, are as follows (in millions):

Maturity date	Amount
2016	$2,250
2017	4,300
2018	2,075
2019	3,383
2020	1,950
Thereafter	17,682
Total	$31,640

Interest costs

Interest costs are expensed as incurred, except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest expense, net, for the years ended December 31, 2015, 2014 and 2013, was $1.1 billion, $1.1 billion and $1.0 billion, respectively. Interest costs capitalized for the years ended December 31, 2015, 2014 and 2013, were not material. Interest paid, including the ongoing impact and settlements of interest rate and cross currency swaps, during the years ended December 31, 2015, 2014 and 2013, totaled $1.0 billion, $1.1 billion and $1.1 billion, respectively.

15. Stockholders' equity

Stock repurchase program

Activity under our stock repurchase program was as follows (in millions):

	During the years ended December 31,					
	2015		2014		2013	
	Shares	Dollars	Shares	Dollars	Shares	Dollars
First quarter	2.9	$451	—	$—	9.1	$771
Second quarter	3.3	515	—	—	—	—
Third quarter	4.6	703	—	—	—	—
Fourth quarter	1.2	184	0.9	153	—	—
Total stock repurchases	12.0	$1,853	0.9	$153	9.1	$771

In October 2015, our Board of Directors authorized an increase that resulted in a total of $5.0 billion available under our stock repurchase program. As of December 31, 2015, $4.9 billion, remained available under our stock repurchase program.

Dividends

Our Board of Directors declared quarterly dividends per share of $0.79, $0.61, and $0.47 that were paid in each of the four quarters of 2015, 2014, and 2013, respectively.

Historically, each year we have declared dividends in December that were paid in the first quarter of the following fiscal year, and in March, July and October that were paid in the second, third and fourth quarters, respectively, of the same fiscal year.

Additionally, on December 15, 2015, the Board of Directors declared a quarterly cash dividend of $1.00 per share of common stock, which will be paid on March 8, 2016, to all stockholders of record as of the close of business on February 16, 2016.

Accumulated other comprehensive income

The components of accumulated other comprehensive income (AOCI) were as follows (in millions):

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2012	$12	$(35)	$ 183	$(14)	$146
Foreign currency translation adjustments	(71)	—	—	—	(71)
Unrealized gains (losses)	—	88	(284)	(1)	(197)
Reclassification adjustments to income	—	(85)	(75)	—	(160)
Other	—	—	—	(2)	(2)
Income taxes	(9)	(1)	133	—	123
Balance as of December 31, 2013	(68)	(33)	(43)	(17)	(161)
Foreign currency translation adjustments	(218)	—	—	—	(218)
Unrealized gains	—	298	37	1	336
Reclassification adjustments to income	—	203	1	—	204
Other	—	—	—	1	1
Income taxes	22	(178)	(14)	—	(170)
Balance as of December 31, 2014	(264)	290	(19)	(15)	(8)
Foreign currency translation adjustments	(257)	—	—	—	(257)
Unrealized gains (losses)	—	150	(299)	8	(141)
Reclassification adjustments to income	—	(143)	76	—	(67)
Other	—	—	—	1	1
Income taxes	10	—	(18)	—	(8)
Balance as of December 31, 2015	$(511)	$297	$ (260)	$(6)	$(480)

Income tax expenses/benefits for unrealized gains and losses and the related reclassification adjustments to income for cash flow hedges were a $53 million expense and $53 million benefit in 2015, a $104 million expense and $74 million expense in 2014 and a $34 million expense and $33 million benefit in 2013, respectively. Income tax expenses/benefits for unrealized gains and losses and the related reclassification adjustments to income for available-for-sale securities were a $0 million and $18 million expense for 2015, a $14 million expense and $0 million in 2014 and a $105 million benefit and $28 million benefit in 2013, respectively.

The reclassifications out of AOCI to earnings were as follows (in millions):

Components of AOCI	Amounts reclassified out of AOCI Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013	Line item affected in the Statements of Income
Cash flow hedges:				
Foreign currency contract gains	$326	$28	$4	Product sales
Cross-currency swap contract (losses) gains	(182)	(230)	82	Interest and other income, net
Forward interest rate contract losses	(1)	(1)	(1)	Interest expense, net
	143	(203)	85	Total before income tax
	(53)	74	(33)	Tax benefit (expense)
	$90	$(129)	$52	Net of taxes
Available-for-sale securities:				
Net realized (losses) gains	$(76)	$(1)	$75	Interest and other income, net
	18	—	(28)	Tax benefit (expense)
	$(58)	$(1)	$47	Net of taxes

Other

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. As of December 31, 2015 and 2014, no shares of preferred stock were issued or outstanding.

16. Fair value measurement

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

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

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

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

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

The fair value of each major class of the Company's financial assets and liabilities measured at fair value on a recurring basis was as follows (in millions):

Fair value measurement as of December 31, 2015, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale investments:				
U.S. Treasury securities	$ 4,274	$ —	$—	$4,274
Other government-related debt securities:				
U.S.	—	534	—	534
Foreign and other	—	1,739	—	1,739
Corporate debt securities:				
Financial	—	7,871	—	7,871
Industrial	—	7,836	—	7,836
Other	—	885	—	885
Residential mortgage-backed securities	—	1,470	—	1,470
Other mortgage- and asset-backed securities	—	2,469	—	2,469
Money market mutual funds	3,370	—	—	3,370
Other short-term interest bearing securities	—	528	—	528
Equity securities	136	—	—	136
Derivatives:				
Foreign currency contracts	—	142	—	142
Interest rate swap contracts	—	71	—	71
Total assets	$ 7,780	$ 23,545	$—	$31,325
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 8	$—	$8
Cross-currency swap contracts	—	250	—	250
Interest rate swap contracts	—	3	—	3
Contingent consideration obligations in connection with business combinations	—	—	188	188
Total liabilities	$ —	$ 261	$188	$449

Fair value measurement as of December 31, 2014, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale investments:				
U.S. Treasury securities	$ 3,646	$—	$—	$3,646
Other government-related debt securities:				
U.S.	—	528	—	528
Foreign and other	—	1,569	—	1,569
Corporate debt securities:				
Financial	—	6,041	—	6,041
Industrial	—	6,351	—	6,351
Other	—	649	—	649
Residential mortgage-backed securities	—	1,702	—	1,702
Other mortgage- and asset-backed securities	—	1,796	—	1,796
Money market mutual funds	3,004	—	—	3,004
Other short-term interest-bearing securities	—	1,302	—	1,302
Equity securities	144	—	—	144
Derivatives:				
Foreign currency contracts	—	360	—	360
Cross-currency swap contracts	—	32	—	32
Interest rate swap contracts	—	46	—	46
Total assets	$ 6,794	$20,376	$—	$27,170
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$4	$—	$4
Cross-currency swap contracts	—	12	—	12
Interest rate swap contracts	—	26	—	26
Contingent consideration obligations in connection with business combinations	—	—	215	215
Total liabilities	$ —	$42	$215	$257

The fair values of our U.S. Treasury securities, money market mutual funds and equity securities are based on quoted market prices in active markets with no valuation adjustment.

Most of our other government-related and corporate debt securities are investment grade with maturity dates of five years or less from the balance sheet date. Our other government-related debt securities portfolio is composed of securities with weighted-average credit ratings of A or equivalent by S&P, Moody's or Fitch, Inc. (Fitch); and our corporate debt securities portfolio has a weighted-average credit rating of BBB+ or equivalent by S&P or Moody's and A- by Fitch. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

Our residential mortgage-, other mortgage- and asset-backed securities portfolio is composed entirely of senior tranches, with credit ratings of AAA by S&P, Moody's or Fitch. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and

broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

We value our other short-term interest-bearing securities at amortized cost, which approximates fair value given their near term maturity dates.

All of our foreign currency forward and option derivatives contracts have maturities of three years or less and all are with counterparties that have minimum credit ratings of A- or equivalent by S&P, Moody's or Fitch. We estimated the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable, either directly or indirectly. These inputs include foreign currency rates, LIBOR cash and swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts also include implied volatility measures. These inputs, where applicable, are at commonly quoted intervals. See Note 17, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A- or equivalent by S&P, Moody's or Fitch. We estimated the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. See Note 17, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A- or equivalent by S&P, Moody's or Fitch. We estimated the fair values of these contracts by using an income-based industry standard valuation model for which all significant inputs were observable either directly or indirectly. These inputs included LIBOR, swap rates and obligor credit default swap rates.

Contingent consideration obligations

We have incurred contingent consideration obligations as a result of our acquisition of a business and upon the assumption of contingent consideration obligations incurred by an acquired company discussed below. These contingent consideration obligations are recorded at their estimated fair values, and we revalue these obligations each reporting period until the related contingencies are resolved. The fair value measurements of these obligations are based on significant unobservable inputs related to product candidates acquired in the business combinations and are reviewed quarterly by management in our R&D and commercial sales organizations. These inputs include, as applicable, estimated probabilities and timing of achieving specified regulatory and commercial milestones and estimated annual sales. Significant changes which increase or decrease the probabilities of achieving the related regulatory and commercial events, shorten or lengthen the time required to achieve such events, or increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of these obligations, as applicable. Changes in fair values of contingent consideration obligations are recognized in Other operating expenses in the Consolidated Statements of Income.

The changes in carrying amounts of contingent consideration obligations were as follows (in millions):

	During the years ended December 31,	
	2015	2014
Beginning balance	$215	$595
Additions from Dezima acquisition	110	—
Net changes in valuation	(12)	(30)
Agreement with former Proteolix, Inc. shareholders	—	(225)
Payment to former BioVex Group, Inc. shareholders	(125)	(125)
Ending balance	$188	$215

As a result of our acquisition of Dezima in October 2015, we are obligated to pay its former shareholders up to $1.25 billion of additional consideration contingent upon achieving certain development and sales-related milestones and low single-digit royalties on net product sales above a certain threshold. The estimated fair values of the contingent consideration obligations had an aggregate value of $110 million at acquisition. See Note 3, Business combinations. We estimate the fair values of the obligations to the former shareholders of Dezima by using probability-adjusted discounted cash flows and review underlying key assumptions on a quarterly basis. There was no significant change in the fair values of this contingent consideration obligation from the date of our acquisition of Dezima to December 31, 2015.

As a result of our acquisition of BioVex in March 2011, we were obligated to pay its former shareholders up to $575 million of additional consideration contingent upon achieving separate regulatory and sales-related milestones with regard to IMLYGIC™. We made milestone payments of $125 million in 2014 as a result of filing a Biologics License Application (BLA) in the United States and $125 million in 2015 as a result of the first commercial sale of IMLYGIC™ in the United States following marketing approval. The remaining milestone payments of up to $325 million will become payable if certain sales thresholds are achieved within specified periods of time.

We estimate the fair values of the obligations to the former shareholders of BioVex by using probability-adjusted discounted cash flows and review underlying key assumptions on a quarterly basis. There were no significant changes in the estimated aggregate fair value of the contingent consideration obligations for the years ended December 31, 2015 and 2014.

As a result of our acquisition of Onyx in October 2013, we assumed contingent consideration obligations arising from Onyx's 2009 acquisition of Proteolix, Inc. See Note 3, Business combinations. In December 2014, we renegotiated and settled the contingent consideration obligations with the former shareholders of Proteolix, Inc. by agreeing to make a single payment of $225 million which was made in the first quarter of 2015. During the year ended December 31, 2014, the change in the fair values of these contingent consideration obligations was not significant.

There have been no transfers of assets or liabilities between the fair value measurement levels, and there were no material remeasurements to fair value during the years ended December 31, 2015 and 2014, of assets and liabilities that are not measured at fair value on a recurring basis.

Summary of the fair value of other financial instruments

Cash equivalents

The estimated fair values of cash equivalents approximate their carrying values due to the short-term nature of these financial instruments.

Borrowings

We estimated the fair value of our long-term debt (Level 2) by taking into consideration indicative prices obtained from a third-party financial institution that utilizes industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; credit spreads; benchmark yields; foreign currency exchange rates, as applicable; and other observable inputs. As of December 31, 2015 and 2014, the aggregate fair values of our long-term debt were $33.1 billion and $33.6 billion, respectively, and the carrying values were $31.6 billion and $30.7 billion, respectively.

17. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to these exposures, we utilize or have utilized certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We do not use derivatives for speculative trading purposes.

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, associated primarily with our euro-denominated international product sales. Increases and decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are offset partially by corresponding increases and decreases in our international operating expenses resulting from these foreign currency exchange rate movements. To further reduce our exposure to foreign currency exchange rate fluctuations on our international product sales, we enter into foreign currency forward and option contracts to hedge a portion of our projected international product sales primarily over a three-year time horizon, with, at any given point in time, a higher percentage of nearer-term projected product sales being hedged than in successive periods.

As of December 31, 2015, 2014 and 2013, we had open foreign currency forward contracts with notional amounts of $3.3 billion, $3.8 billion and $4.0 billion, respectively, and open foreign currency option contracts with notional amounts of $225 million, $271 million and $516 million, respectively. We have designated these foreign currency forward and option contracts, primarily euro based, as cash flow hedges, and accordingly, we report the effective

portions of the unrealized gains and losses on

these contracts in AOCI on the Consolidated Balance Sheets and reclassify them to earnings in the same periods during which the hedged transactions affect earnings.

To manage counterparty risk resulting from favorable movements in U.S. dollar/foreign currency exchange rates, we effectively terminated outstanding foreign currency forward and option contracts with a notional amount of $2.3 billion during the year ended December 31, 2015. We received $340 million from the counterparties, which was included in Net cash provided by operating activities in the Consolidated Statement of Cash Flows. This amount remains in AOCI and will be recognized in Product sales in the Consolidated Statements of Income when the related international product sales affect earnings. In addition, during the year ended December 31, 2015, we entered into new foreign currency forward and option contracts that hedge these forecasted international product sales. These contracts are included in the notional amounts of cash flow hedges outstanding as of December 31, 2015.

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. Under the terms of these contracts, we paid euros/pounds sterling and received U.S. dollars for the notional amounts at the inception of the contracts, and we exchange interest payments based on these notional amounts at fixed rates over the lives of the contracts in which we pay U.S. dollars and receive euros/pounds sterling. In addition, we will pay U.S. dollars to and receive euros/pounds sterling from the counterparties at the maturities of the contracts for these same notional amounts. The terms of these contracts correspond to the related hedged notes, effectively converting the interest payments and principal repayment on these notes from euros/pounds sterling to U.S. dollars. We have designated these cross-currency swap contracts as cash flow hedges, and accordingly, the effective portions of the unrealized gains and losses on these contracts are reported in AOCI on the Consolidated Balance Sheets and reclassified to earnings in the same periods during which the hedged debt affects earnings.

The notional amounts and interest rates of our cross-currency swaps are as follows (notional amounts in millions):

	Foreign currency			U.S. dollars		
Hedged notes	Notional amount	Interest rate		Notional amount	Interest rate	
2.125% 2019 euro Notes	€675	2.125	%	$864	2.6	%
5.50% 2026 pound sterling Notes	£475	5.50	%	$747	6.0	%
4.00% 2029 pound sterling Notes	£700	4.00	%	$1,111	4.5	%

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on such contracts, which are designated as cash flow hedges, are reported in AOCI in the Consolidated Balance Sheets and amortized into earnings over the lives of the associated debt issuances.

The effective portions of the unrealized gain/(loss) recognized in other comprehensive income for our derivative instruments designated as cash flow hedges were as follows (in millions):

	Years ended December 31,		
Derivatives in cash flow hedging relationships	2015	2014	2013
Foreign currency contracts	$425	$452	$(44)
Cross-currency swap contracts	(275)	(154)	132
Total	$150	$298	$88

The locations in the Consolidated Statements of Income and the effective portions of the gain/(loss) reclassified out of AOCI into earnings for our derivative instruments designated as cash flow hedges were as follows (in millions):

		Years ended December 31,		
Derivatives in cash flow hedging relationships	Statements of Income location	2015	2014	2013
Foreign currency contracts	Product sales	$326	$28	$4
Cross-currency swap contracts	Interest and other income, net	(182)	(230)	82
Forward interest rate contracts	Interest expense, net	(1)	(1)	(1)
Total		$143	$(203)	$85

No portions of our cash flow hedge contracts are excluded from the assessment of hedge effectiveness, and the gains and losses of the ineffective portions of these hedging instruments were not material for the years ended December 31, 2015, 2014 and 2013. As of December 31, 2015, the amounts expected to be reclassified out of AOCI into earnings over the next 12 months are approximately $311 million of net gains on our foreign currency and cross-currency swap contracts and approximately $1 million of losses on forward interest rate contracts.

Fair value hedges

To achieve a desired mix of fixed and floating interest rates on our long-term debt, we entered into interest rate swap contracts, which qualified and are designated as fair value hedges. The terms of these interest rate swap contracts correspond to the related hedged debt instruments and effectively converted a fixed interest rate coupon to a floating LIBOR-based coupon over the lives of the respective notes. During the year ended December 31, 2014, we entered into interest rate swap contracts with an aggregate notional amount of $2.25 billion with respect to our 1.25% 2017 Notes and our 2.20% 2019 Notes. The contracts have rates that range from three-month LIBOR plus 0.4% to three-month LIBOR plus 0.6%. During the year ended December 31, 2013, we entered into interest rate swap contracts with an aggregate notional amount of $4.4 billion with respect to our 3.45% 2020 Notes, 4.10% 2021 Notes, 3.875% 2021 Notes and 3.625% 2022 Notes. The contracts have rates that range from three-month LIBOR plus 1.1% to three-month LIBOR plus 2.0%. As of December 31, 2015 and 2014, we had interest rate swap agreements with aggregate notional amounts of $6.65 billion.

For derivative instruments that qualify for and are designated as fair value hedges, we recognize in current earnings the unrealized gain or loss on the derivative resulting from the change in fair value during the period as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. During the years ended December 31, 2015 and 2014, we included the unrealized losses on the hedged debt of $48 million and $181 million, respectively, in the same line item, Interest expense, net, in the Consolidated Statements of Income, as the offsetting unrealized gains of $48 million and $181 million, respectively, on the related interest rate swap agreements. During the year ended December 31, 2013, we included the unrealized gains on the hedged debt of $161 million in the same line item, Interest expense, net, in the Consolidated Statement of Income, as the offsetting unrealized losses of $161 million on the related interest rate swap agreements.

Derivatives not designated as hedges

We enter into foreign currency forward contracts that are not designated as hedging transactions to reduce our exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies. These exposures are hedged on a month-to-month basis. As of December 31, 2015, 2014 and 2013, the total notional amounts of these foreign currency forward contracts were $911 million, $875 million and $999 million, respectively.

The location in the Consolidated Statements of Income and the amount of gain/(loss) recognized in earnings for our derivative instruments not designated as hedging instruments were as follows (in millions):

		Years ended December 31,		
Derivatives not designated as hedging instruments	Statements of Income location	2015	2014	2013
Foreign currency contracts	Interest and other income, net	$(16)	$(10)	$15

The fair values of derivatives included on the Consolidated Balance Sheets were as follows (in millions):

	Derivative assets		Derivative liabilities	
December 31, 2015	Balance Sheet location	Fair value	Balance Sheet location	Fair value
Derivatives designated as hedging instruments:				
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	$—	Accrued liabilities/ Other noncurrent liabilities	$250
Foreign currency contracts	Other current assets/ Other noncurrent assets	142	Accrued liabilities/ Other noncurrent liabilities	7
Interest rate swap contracts	Other current assets/ Other noncurrent assets	71	Accrued liabilities/ Other noncurrent liabilities	3
Total derivatives designated as hedging instruments		213		260
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	—	Accrued liabilities	1
Total derivatives not designated as hedging instruments		—		1
Total derivatives		$213		$261
	Derivative assets		Derivative liabilities	
December 31, 2014	Balance Sheet location	Fair value	Balance Sheet location	Fair value
Derivatives designated as hedging instruments:				
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	$32	Accrued liabilities/ Other noncurrent liabilities	$12
Foreign currency contracts	Other current assets/ Other noncurrent assets	356	Accrued liabilities/ Other noncurrent liabilities	—
Interest rate swap contracts	Other current assets/ Other noncurrent assets	46	Accrued liabilities/ Other noncurrent liabilities	26
Total derivatives designated as hedging instruments		434		38
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	4	Accrued liabilities	4
Total derivatives not designated as hedging instruments		4		4
Total derivatives		$438		$42

Our derivative contracts that were in liability positions as of December 31, 2015, contain certain credit-risk-related contingent provisions that would be triggered if: (i) we were to undergo a change in control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that

approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due to or from a counterparty under these contracts may only be offset against other amounts due to or from the same counterparty if an event of default or termination, as defined, were to occur.

The cash flow effects of our derivative contracts for the three years ended December 31, 2015, are included within Net cash provided by operating activities in the Consolidated Statements of Cash Flows.

18. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings and other matters—including those discussed in this Note—that are complex in nature and have outcomes that are difficult to predict.

We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Our legal proceedings range from cases brought by a single plaintiff to class actions with thousands of putative class members. These legal proceedings, as well as other matters, involve various aspects of our business and a variety of claims—including but not limited to patent infringement, marketing, pricing and trade practices and securities law—some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing, plaintiffs seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process (which in complex proceedings of the sort faced by us often extend for several years). As a result, none of the matters pending against us described in this filing have progressed sufficiently through discovery and/or development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these 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.

Certain of our legal proceedings and other matters are discussed below:

Sanofi/Regeneron Patent Litigation

On October 17, 2014, Amgen initiated a series of lawsuits in the U.S. District Court of Delaware (the Delaware District Court) against Sanofi, Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc. (collectively Sanofi), and Regeneron Pharmaceuticals, Inc. (Regeneron) for patent infringement. On December 15, 2014, these lawsuits were consolidated by the Delaware District Court into a single case, which now addresses seven of our patents: U.S. Patent Nos. 8,563,698; 8,829,165; 8,859,741; 8,871,913; 8,871,914; 8,883,983; and 8,889,834. These patents describe and claim monoclonal antibodies to proprotein convertase subtilisin/kexin type 9 (PCSK9). By its complaints, Amgen seeks an injunction to prevent the infringing manufacture, use and sale of Sanofi and Regeneron's alirocumab, a monoclonal antibody targeting PCSK9. On January 29, 2016, the Delaware District Court granted Amgen's motion to amend the complaint to add Amgen Manufacturing, Limited and Amgen USA Inc. as plaintiffs and to add the allegation that defendants' infringement of Amgen's patents is willful. The trial date has been set for March 7, 2016.

Biosimilars Patent Litigations

We have filed a number of lawsuits against manufacturers of products that purport to be biosimilars of certain of our products. In each case, our complaint alleges that the manufacturer's actions infringe certain patents we hold and that the manufacturer has failed to comply with certain provisions of the Biologics Price Competition and Innovation Act (BPCIA).

Sandoz Filgrastim Litigation

On October 24, 2014, Amgen and Amgen Manufacturing, Limited (collectively Amgen) filed a lawsuit in the U.S. District Court for the Northern District of California (the California Northern District Court) against Sandoz Inc., Sandoz International GmbH and Sandoz GmbH (collectively Sandoz) for infringement of our U.S. Patent No. 6,162,427 and various state law claims. The lawsuit stems from Sandoz filing an application for FDA licensure of a filgrastim product as biosimilar to NEUPOGEN® under the BPCIA, while having deliberately failed to comply with the BPCIA's disclosure requirement to Amgen as the reference product sponsor. By its complaint, Amgen sought, amongst other remedies, an injunction to cease Sandoz's unauthorized reliance on Amgen's biological license for filgrastim, including an order compelling Sandoz to suspend FDA review of their application until there is restitution

for its non-compliance with the BPCIA, an injunction to prevent Sandoz from commercially marketing the biosimilar product until Amgen is restored to the position it would have been in had Sandoz met their obligations under the BPCIA and an injunction to prevent Sandoz from infringing, or inducing any infringing use of, filgrastim.

On March 19, 2015, the California Northern District Court issued an order dismissing with prejudice Amgen's state law claims, and entered judgment in favor of Sandoz Inc. on its cross-motion for partial judgment on the pleadings. The order also denied Amgen's motion for a preliminary injunction, as well as Amgen's motion for partial judgment on the pleadings. On a joint motion of the parties, on March 25, 2015, the California Northern District Court entered final judgment on the claims and counterclaims decided by the court's March 19 order. The remaining patent infringement claim, counterclaim and defenses were stayed by the court pending appeal. On March 25, 2015, Amgen appealed the judgment in favor of Sandoz Inc. and the denial of Amgen's motion for preliminary injunction to the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court). On May 5, 2015, the Federal Circuit Court entered an injunction prohibiting Sandoz Inc. from marketing, selling, offering for sale, or importing into the United States Sandoz's FDA-approved Zarxio™ biosimilar product until the Federal Circuit Court resolved the appeal.

On July 21, 2015, the Federal Circuit Court affirmed the district court's dismissal of Amgen's state law claims and directed the California Northern District Court to enter judgment on Sandoz's counter-claims consistent with the Federal Circuit's interpretation of the BPCIA. The Federal Circuit Court concluded that the only remedies available for a biosimilar applicant's failure to provide its BLA by the statutory deadline is to bring a patent infringement claim and seek those patent remedies provided by the statute. The Federal Circuit Court also concluded that a biosimilar applicant must give 180-day advance notice of first commercial marketing after the FDA has licensed the biosimilar product. Accordingly, the Federal Circuit Court entered an order that its previously entered injunction be extended through September 2, 2015, (180 days from Sandoz Inc.'s notice given after FDA approval) and remanded for the district court to consider the patent infringement claim and counterclaims. Sandoz launched Zarxio™ in the United States on September 3, 2015.

On August 20, 2015, Amgen and Sandoz each petitioned the Federal Circuit Court requesting rehearing en banc of various aspects of the Federal Circuit Court opinion on which the other had prevailed. On October 16, 2015, the Federal Circuit Court denied each of Amgen's and Sandoz's petitions for rehearing en banc.

On September 8, 2015, the California Northern District Court granted the parties' joint motion to lift the stay of the case, allowing the remaining patent infringement claim, counterclaim and defenses to proceed. Amgen filed a first supplemental and amended complaint on October 15, 2015, adding to the lawsuit Sandoz's infringement of U.S. Patent No. 8,940,878, which covers methods of purifying proteins. A claim construction hearing is scheduled for May 4, 2016.

Apotex Pegfilgrastim/Filgrastim Litigation

On August 6, 2015, Amgen filed a lawsuit in the U.S. District Court for the Southern District of Florida (the Florida Southern District Court) against Apotex Inc. and Apotex Corp. (collectively Apotex) for infringement of our U.S. Patent Nos. 8,952,138 (the `138 Patent) and 5,824,784 (the `784 Patent) in accordance with the patent provisions of the BPCIA and for a declaration that Apotex's pre-licensure notice of commercial marketing is legally ineffective. This lawsuit stems from Apotex's submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen's Neulasta®. By its complaint, Amgen seeks, amongst other remedies, an injunction prohibiting Apotex from infringing the `138 and `784 patents and enjoining Apotex from commencing commercial marketing of any biosimilar pegfilgrastim product until a date that is at least 180 days after Apotex provides legally effective notice to Amgen. Apotex answered the complaint on October 5, 2015, denying patent infringement, alleging that the patents are invalid, alleging sham litigation in violation of the Sherman Antitrust Act, seeking a declaration that the `138 patent is unenforceable for patent misuse and seeking a declaration on the interpretation of the BPCIA commercial notice provision.

On October 2, 2015, Amgen filed a second lawsuit in the Florida Southern District Court against Apotex for infringement of the `138 Patent and our U.S. Patent No. 6,162,427 (the `427 Patent) and in accordance with the patent provisions of the BPCIA and for a declaration that Apotex's pre-licensure notice of commercial marketing is legally ineffective. This lawsuit stems from Apotex's submission of an application for FDA licensure of a filgrastim product as biosimilar to NEUPOGEN®. By its complaint, Amgen seeks, amongst other remedies, an injunction prohibiting Apotex from infringing the `138 and `427 patents and enjoining Apotex from commencing commercial marketing of any biosimilar filgrastim product until a date that is at least 180 days after Apotex provides legally effective notice to Amgen. On November 3, 2015, the Florida Southern District Court consolidated the two lawsuits into a single case.

On December 9, 2015, the Florida Southern District Court granted Amgen's motion for preliminary injunction prohibiting Apotex from commercializing its biosimilar pegfilgrastim product until a date that is at least 180 days after Apotex provides legally effective commercial notice to Amgen. On December 19, 2015, Apotex appealed this injunction to the Federal Circuit Court. The patent litigation is proceeding in the Florida Southern District Court during the pendency of the appeal and trial is scheduled for July 11, 2016.

Hospira Epoetin Alfa Litigation

On September 18, 2015, Amgen filed a lawsuit in the Delaware District Court against Hospira, Inc. (Hospira), a subsidiary of Pfizer, for infringement of our U.S. Patent Nos. 5,856,298 (the `298 Patent) and 5,756,349 (the `349 Patent) in accordance with the patent provisions of the BPCIA and for a declaration that Hospira has failed to comply with certain requirements of the BPCIA. This lawsuit stems from the submission by Hospira under the BPCIA of an application for FDA licensure of an epoetin product as biosimilar to Amgen's EPOGEN®. Amgen seeks a declaration that the BPCIA requires that Hospira provide Amgen with notice of commercial marketing 180 days before it first begins commercial marketing of any biosimilar epoetin product and that this notice can only be given after the FDA has licensed Hospira's biosimilar product. By its complaint, Amgen seeks, amongst other remedies, an injunction prohibiting Hospira from using or selling infringing cells and/or product manufactured during the `298 or the `349 patent terms and enjoining Hospira from commencing commercial marketing of any biosimilar epoetin product until a date that is at least 180 days after Hospira provides legally effective notice to Amgen.

On November 12, 2015, Hospira filed a motion to dismiss the one count of Amgen's complaint which seeks a declaration that Hospira has failed to comply with the notice requirements of the BPCIA. A hearing on the motion to dismiss has been set for February 16, 2016.

Onyx Litigation

Between August 28, 2013 and September 16, 2013, nine plaintiffs filed purported class action lawsuits against Onyx, its directors, Amgen and Arena Acquisition Company (Arena), and unnamed "John Doe" defendants in connection with Amgen's acquisition of Onyx. Seven of those purported class actions were brought in the Superior Court of the State of California for the County of San Mateo (the San Mateo County Superior Court), captioned Lawrence I. Silverstein and Phil Rosen v. Onyx Pharmaceuticals, Inc., et al. (August 28, 2013) ("Silverstein"), Laura Robinson v. Onyx Pharmaceuticals, Inc., et al. (originally filed in the Superior Court for the County of San Francisco on August 28, 2013, and re-filed in the San Mateo County Superior Court on August 29, 2013) ("Robinson"), John Solak v. Onyx Pharmaceuticals, Inc., et al. (August 30, 2013) ("John Solak"), Louisiana Municipal Police Employees' Retirement System and Hubert Chow v. Onyx Pharmaceuticals, Inc., et al. (September 3, 2013) ("Louisiana Municipal"), Laurine Jonopulos v. Onyx Pharmaceuticals, Inc., et al. (September 4, 2013) ("Jonopulos"), Clifford G. Martin v. Onyx Pharmaceuticals, Inc., et al. (September 9, 2013) ("Martin") and Merrill L. Magowan v. Onyx Pharmaceuticals, Inc. et al. (September 9, 2013) ("Magowan"). The eighth and ninth purported class actions were brought in the Court of Chancery of the State of Delaware, captioned Mark D. Smilow, IRA v. Onyx Pharmaceuticals Inc., et al. (August 29, 2013) ("Smilow") and William L. Fitzpatric v. Onyx Pharmaceuticals, Inc., et al. (September 16, 2013) ("Fitzpatric"). On September 5, 2013, the plaintiff in the John Solak case dismissed his case. On September 10, 2013, the plaintiff in the Smilow case dismissed his case. On September 10, 2013, plaintiffs in the Silverstein and Louisiana Municipal cases filed an amended complaint alleging substantially the same claims and seeking substantially the same relief as in their individual purported class action lawsuits. Each of the lawsuits alleges that the Onyx director defendants breached their fiduciary duties to Onyx shareholders, and that the other defendants aided and abetted such breaches, by seeking to sell Onyx through an allegedly unfair process and for an unfair price and on unfair terms. The Magowan and Fitzpatric complaints and the amended complaint filed in the Silverstein and Louisiana Municipal cases also alleged that the individual defendants breached their fiduciary duties with respect to the contents of the tender offer solicitation material. Each of the lawsuits sought, among other things, rescission of the merger agreement and attorneys' fees and costs, and certain of the lawsuits sought other relief. The Silverstein, Robinson, Louisiana Municipal and Jonopulos cases were designated as "complex" and assigned to the Honorable Marie S. Weiner of the San Mateo County Superior Court, who subsequently entered an order consolidating the Silverstein, Robinson, Louisiana Municipal, Jonopulos, Martin and Magowan cases (the Consolidated Cases). On October 31, 2013, the plaintiffs in the Consolidated Cases filed a consolidated class action complaint seeking certification of a class and alleging breach of fiduciary duties of loyalty and good faith against the Onyx directors and aiding and abetting breach of fiduciary duties against Onyx. The complaint sought certification of a class of all Onyx shareholders, damages (including pre- and post-judgment interest), attorneys' fees and expenses plus other relief. The plaintiffs in the Consolidated Cases simultaneously filed a notice of dismissal without prejudice of Amgen and Arena. On January 9, 2014, the court sustained a demurrer without leave to amend as to Onyx. The plaintiff in the Fitzpatric case dismissed his case on

August 22, 2014. On January 30, 2015, the court granted class certification and appointed Mr. Rosen as class representative in the Consolidated Cases. A hearing on defendants' summary judgment motion has been set for February 24, 2016, and the trial date has been set for April 28, 2016.

Federal Securities Litigation - In re Amgen Inc. Securities Litigation

The six federal class action stockholder complaints filed against Amgen, Kevin W. Sharer, Richard D. Nanula, Dennis M. Fenton, Roger M. Perlmutter, Brian M. McNamee, George J. Morrow, Edward V. Fritzky, Gilbert S. Omenn and Franklin P. Johnson, Jr., (the Federal Defendants) in the U.S. District Court for the Central District of California (the California Central District

Court) on April 17, 2007 (Kairalla v. Amgen Inc., et al.), May 1, 2007 (Mendall v. Amgen Inc., et al., & Jaffe v. Amgen Inc., et al.), May 11, 2007 (Eldon v. Amgen Inc., et al.), May 21, 2007 (Rosenfield v. Amgen Inc., et al.) and June 18, 2007 (Public Employees' Retirement Association of Colorado v. Amgen Inc., et al.) were consolidated by the California Central District Court into one action captioned In re Amgen Inc. Securities Litigation. The consolidated complaint was filed with the California Central District Court on October 2, 2007. The consolidated complaint alleges that Amgen and these officers and directors made false statements that resulted in: (i) deceiving the investing public regarding Amgen's prospects and business; (ii) artificially inflating the prices of Amgen's publicly traded securities and (iii) causing plaintiff and other members of the class to purchase Amgen publicly traded securities at inflated prices. The complaint also makes off-label marketing allegations that, throughout the class period, the Federal Defendants improperly marketed Aranesp® and EPOGEN® for off-label uses while aware that there were alleged safety signals with these products. The plaintiffs seek class certification, compensatory damages, legal fees and other relief deemed proper. On February 4, 2008, the California Central District Court granted in part, and denied in part, the Federal Defendants' motion to dismiss the consolidated amended complaint. Specifically, the California Central District Court granted the Federal Defendants' motion to dismiss as to individual defendants Fritzky, Omenn, Johnson, Fenton and McNamee, but denied the Federal Defendants' motion to dismiss as to individual defendants Sharer, Nanula, Perlmutter and Morrow.

On August 12, 2009, the California Central District Court granted plaintiffs' motion for class certification. On April 14, 2014, the California Central District Court entered an order allowing plaintiffs leave to file a second consolidated amended class action complaint. While the new complaint was filed under seal, like the first consolidated class action complaint the new complaint continues to assert that the Federal Defendants made false statements and engaged in off-label marketing causing the same results as alleged in the first consolidated class action complaint. The complaint continues to name the same Federal Defendants and the alleged class period remains the same. Plaintiffs continue to seek compensatory damages, legal fees and other relief deemed proper. On May 5, 2014, plaintiffs filed an unsealed, redacted version of their second consolidated amended complaint. On August 4, 2014, the court issued an order granting the Federal Defendants' motion to dismiss with respect to certain of the misrepresentations alleged in the complaint and otherwise denying the motion to dismiss. Following the court's order, the complaint continues to assert that the Federal Defendants made false statements and engaged in off-label marketing causing the same results as alleged in the first consolidated class action complaint. The complaint continues to name the same Federal Defendants and the alleged class period remains the same. The trial date has been set for July 12, 2016.

State Derivative Litigation

The three state stockholder derivative complaints filed against Amgen, Kevin W. Sharer, George J. Morrow, Dennis M. Fenton, Brian M. McNamee, Roger M. Perlmutter, David Baltimore, Gilbert S. Omenn, Judith C. Pelham, Frederick W. Gluck, Jerry D. Choate, J. Paul Reason, Frank J. Biondi, Jr., Leonard D. Schaeffer, Frank C. Herringer, Richard D. Nanula, Willard H. Dere, Edward V. Fritzky, Franklin P. Johnson, Jr. and Donald B. Rice as defendants (the State Defendants) on May 1, 2007 (Larson v. Sharer, et al., & Anderson v. Sharer, et al.), and August 13, 2007 (Weil v. Sharer, et al.) in the Superior Court of the State of California, Ventura County (the Ventura County Superior Court) were consolidated by the Ventura County Superior Court under one action captioned Larson v. Sharer, et al. The consolidated complaint was filed on July 5, 2007. The complaint alleges that the State Defendants breached their fiduciary duties, wasted corporate assets, were unjustly enriched and violated the California Corporations Code. Plaintiffs allege that the State Defendants failed to disclose and/or misrepresented results of Aranesp® clinical studies, marketed both Aranesp® and EPOGEN® for off-label uses and that these actions or inactions caused stockholders to suffer damages. The complaints also allege insider trading by the State Defendants. The plaintiffs seek treble damages based on various causes of action, reformed corporate governance, equitable and/or injunctive relief, restitution, disgorgement of profits, benefits and other compensation, and legal costs.

An amended consolidated complaint was filed on March 13, 2008, adding Anthony Gringeri as a State Defendant and removing the causes of action for insider selling and misappropriation of information, violation of California Corporations Code Section 25402 and violation of California Corporations Code Section 25403. On July 14, 2008, the Ventura County Superior Court dismissed without prejudice the consolidated state derivative class action. The judge also ordered a stay of any re-filing of an amended complaint until the federal court has determined in the In re Amgen

Inc. Securities Litigation action whether any securities fraud occurred. On July 24, 2013, the plaintiffs filed an amended complaint asserting additional grounds for the defendants' alleged breaches of fiduciary duty. By stipulation of the parties, the case remains stayed pending resolution of the In re Amgen Inc. Securities Litigation action.

Federal Derivative Litigation

On May 7, 2007, the stockholder derivative lawsuit of Durgin v. Sharer, et al., was filed in the California Central District Court and named Amgen, Kevin W. Sharer, George J. Morrow, Dennis M. Fenton, Brian M. McNamee, Roger M. Perlmutter, David Baltimore, Gilbert S. Omenn, Judith C. Pelham, Frederick W. Gluck, Jerry D. Choate, J. Paul Reason, Frank J. Biondi, Jr.,

Leonard D. Schaeffer, Frank C. Herringer, Richard D. Nanula, Edward V. Fritzky and Franklin P. Johnson, Jr. as defendants. The complaint alleges the same claims and requests the same relief as in the three state stockholder derivative complaints now consolidated as Larson v. Sharer, et al. The case has been stayed for all purposes until thirty days after a final ruling on the motion to dismiss by the California Central District Court in the In re Amgen Inc. Securities Litigation action.

On September 21, 2007, the stockholder derivative lawsuit of Rosenblum v. Sharer, et al., was filed in the California Central District Court. This lawsuit was brought by a stockholder who previously made a demand on the Amgen Board on May 14, 2007. The complaint alleges that the defendants breached their fiduciary duties, wasted corporate assets and were unjustly enriched. Plaintiffs allege that the defendants failed to disclose and/or misrepresented results of Aranesp® clinical studies, marketed both Aranesp® and EPOGEN® for off-label uses and that these actions or inactions as well as the Amgen market strategy caused damage to the Company resulting in several inquiries, investigations and lawsuits that are costly to defend. The complaint also alleges insider trading by the defendants. The plaintiffs seek treble damages based on various causes of action, reformed corporate governance, equitable and/or injunctive relief, restitution, disgorgement of profits, benefits and other compensation, and legal costs. Thereafter, on May 1, 2008, plaintiff in Rosenblum v. Sharer, et al., filed an amended complaint which removed Dennis Fenton as a defendant and also eliminated the claims for insider selling by defendants. On July 30, 2008, the California Central District Court granted Amgen and the defendants' motion to dismiss without prejudice and also granted a stay of the case pending resolution of the In re Amgen Inc. Securities Litigation action.

ERISA Litigation

On August 20, 2007, the Employee Retirement Income Security Act (ERISA) class action lawsuit of Harris v. Amgen Inc., et al., was filed in the California Central District Court and named Amgen, Kevin W. Sharer, Frank J. Biondi, Jr., Jerry Choate, Frank C. Herringer, Gilbert S. Omenn, David Baltimore, Judith C. Pelham, Frederick W. Gluck, Leonard D. Schaeffer, Jacqueline Allred, Raul Cermeno, Jackie Crouse, Lori Johnston, Michael Kelly and Charles Bell as defendants. Plaintiffs claim that Amgen and the individual defendants breached their fiduciary duties and their duty of loyalty by continuing to offer the Amgen stock fund as an investment option in the Amgen Retirement and Savings Plan and the Retirement and Savings Plan for Amgen Manufacturing Limited (the Plans) despite the alleged off-label promotion of both Aranesp® and EPOGEN® and despite a number of allegedly undisclosed study results that allegedly demonstrated safety concerns in patients using ESAs. Plaintiffs also allege that defendants breached their obligations under ERISA by not disclosing to plan participants the alleged off-label marketing and study results. On February 4, 2008, the California Central District Court dismissed the complaint with prejudice as to plaintiff Harris, who had filed claims against Amgen. The claims alleged by the second plaintiff, Ramos, were also dismissed but the court granted the plaintiff leave to amend his complaint. On February 1, 2008, the plaintiffs appealed the decision by the California Central District Court to dismiss the claims of both plaintiffs Harris and Ramos to the U.S. Court of Appeals for the Ninth Circuit (the Ninth Circuit Court). On May 19, 2008, plaintiff Ramos in the Harris v. Amgen Inc., et al., action filed another lawsuit captioned Ramos v. Amgen Inc., et al., in the California Central District Court. The lawsuit is another ERISA class action. The Ramos v. Amgen Inc., et al., matter names the same defendants in the Harris v. Amgen Inc., et al., matter plus four new defendants: Amgen Manufacturing Limited, Richard Nanula, Dennis Fenton and the Fiduciary Committee of the Plans. On July 14, 2009, the Ninth Circuit Court reversed the California Central District Court's decision in the Harris matter and remanded the case back to the California Central District Court. In the meantime, a third ERISA class action was filed by Don Hanks on June 2, 2009 in the California Central District Court alleging the same ERISA violations as in the Harris and Ramos lawsuits.

On August 10, 2009, the Harris, Ramos and Hanks matters were consolidated by the California Central District Court into one action captioned Harris, et. al. v. Amgen Inc. Plaintiffs filed an amended complaint on November 11, 2009 and added two additional plaintiffs, Jorge Torres and Albert Cappa. Amgen filed a motion to dismiss the amended/consolidated complaint, and on March 2, 2010, the California Central District Court dismissed the entire lawsuit without prejudice. Plaintiffs filed an amended complaint on March 23, 2010. Amgen then filed another motion to dismiss on April 20, 2010. On June 16, 2010, the California Central District Court entered an order dismissing the entire lawsuit with prejudice. On June 24, 2010, the plaintiffs filed a notice of appeal with the Ninth Circuit Court. On June 4, 2013, the Ninth Circuit Court reversed the decision of the California Central District Court and remanded the

case back to the California Central District Court for further proceedings. On June 18, 2013, Amgen petitioned the Ninth Circuit Court for rehearing and/or rehearing en banc. The Ninth Circuit Court issued an amended opinion and denied Amgen's petition for rehearing and rehearing en banc on October 23, 2013.

On June 30, 2014, the U.S. Supreme Court granted a petition for certiorari filed by Amgen and the other named defendants, vacated the judgment of the Ninth Circuit Court and remanded this case to the Ninth Circuit Court for reconsideration in light of the U.S. Supreme Court's decision in Fifth Third Bancorp v. Dudenhoeffer, decided June 25, 2014. On October 23, 2014, the Ninth Circuit Court reaffirmed its earlier decision of June 4, 2013. On November 13, 2014, Amgen filed a petition for rehearing en banc with the Ninth Circuit Court. On May 26, 2015, the Ninth Circuit Court denied Amgen's petition for rehearing en banc. On January

25, 2016, the U.S. Supreme Court granted Amgen's petition for certiorari, reversed the judgment of the Ninth Circuit Court and remanded the case back to the California Central District Court for further proceedings.

Commitments

We lease certain facilities and equipment related primarily to administrative, R&D, sales and marketing activities under non-cancelable operating leases that expire through 2032. The following table summarizes the minimum future rental commitments under non-cancelable operating leases as of December 31, 2015 (in millions):

2016	$127
2017	117
2018	107
2019	101
2020	98
Thereafter	199
Total minimum operating lease commitments	$749

Included in the table above are future rental commitments for abandoned leases in the amount of $327 million. There were no material charges for lease abandonments related to the restructuring plan that commenced in 2014 (see Note 2, Restructuring and other cost saving initiatives). Rental expense on operating leases for the years ended December 31, 2015, 2014 and 2013, was $133 million, $126 million and $125 million, respectively.

19. Segment information

We operate in one business segment—human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Enterprise-wide disclosures about product sales; revenues and long-lived assets by geographic area; and revenues from major customers are presented below.

Revenues

Revenues were as follows (in millions):

	Years ended December 31,		
	2015	2014	2013
Product sales:			
ENBREL	$5,364	$4,688	$4,551
Neulasta®	4,715	4,596	4,392
Aranesp®	1,951	1,930	1,911
EPOGEN®	1,856	2,031	1,953
Sensipar®/Mimpara®	1,415	1,158	1,089
XGEVA®	1,405	1,221	1,019
Prolia®	1,312	1,030	744
NEUPOGEN®	1,049	1,159	1,398
Vectibix®	549	505	389
Nplate®	525	469	427
Kyprolis®	512	331	73
Other	291	209	246
Total product sales	20,944	19,327	18,192
Other revenues	718	736	484
Total revenues	$21,662	$20,063	$18,676

Geographic information

Outside the United States, we sell products principally in Europe. The geographic classification of product sales was based on the location of the customer. The geographic classification of all other revenues was based on the domicile of the entity from which the revenues were earned.

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

	Years ended December 31,		
	2015	2014	2013
Revenues:			
United States	$17,167	$15,396	$14,480
Rest of the world (ROW)	4,495	4,667	4,196
Total revenues	$21,662	$20,063	$18,676

	December 31,	
	2015	2014
Long-lived assets:		
United States	$2,275	$2,544
Puerto Rico	1,679	1,771
ROW	953	908
Total long-lived assets	$4,907	$5,223

Major customers

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

We had product sales to three customers each accounting for more than 10% of total revenues for each of the years ended December 31, 2015, 2014 and 2013. For 2015, on a combined basis, these customers accounted for 81% and 97% of worldwide gross revenues and U.S. gross product sales, respectively, as noted in the following table. Certain information with respect to these customers was as follows (dollar amounts in millions):

	Years ended December 31,		
	2015	2014	2013
AmerisourceBergen Corporation:			
Gross product sales	$10,038	$9,142	$8,527
% of total gross revenues	34 %	34 %	35 %
% of U.S. gross product sales	42 %	43 %	44 %
McKesson Corporation:			
Gross product sales	$8,766	$8,011	$6,440
% of total gross revenues	30 %	30 %	27 %
% of U.S. gross product sales	34 %	35 %	32 %
Cardinal Health, Inc.:			
Gross product sales	$5,045	$3,407	$3,209
% of total gross revenues	17 %	13 %	13 %
% of U.S. gross product sales	21 %	16 %	17 %

At December 31, 2015 and 2014, amounts due from these three customers each exceeded 10% of gross trade receivables and accounted for 75% and 69%, respectively, of net trade receivables on a combined basis. At December 31, 2015 and 2014, 23% and 30%, respectively, of trade receivables, net, were due from customers located outside the United States, primarily in Europe. Our total allowance for doubtful accounts as of December 31, 2015 and 2014, was not material.

20. Quarterly financial data (unaudited)

	2015 Quarters ended			
(In millions, except per share data)	December 31	September 30	June 30	March 31
Product sales	$5,329	$5,516	$5,225	$4,874
Gross profit from product sales	4,258	4,482	4,136	3,841
Net income	1,800	1,863	1,653	1,623
Earnings per share:				
Basic	$2.39	$2.46	$2.18	$2.13
Diluted	$2.37	$2.44	$2.15	$2.11

	2014 Quarters ended			
(In millions, except per share data)	December 31	September 30	June 30	March 31
Product sales	$5,174	$4,848	$4,949	$4,356
Gross profit from product sales	3,991	3,780	3,868	3,266
Net income	1,294	1,244	1,547	1,073
Earnings per share:				
Basic	$1.70	$1.63	$2.04	$1.42
Diluted	$1.68	$1.61	$2.01	$1.40

SCHEDULE II
AMGEN INC.
VALUATION AND QUALIFYING ACCOUNTS
Years ended December 31, 2015, 2014 and 2013
(In millions)

Allowance for doubtful accounts	Balance at beginning of period	Additions charged to costs and expenses	Other additions	Deductions	Balance at end of period
Year ended December 31, 2015	$50	$18	$—	$13	$55
Year ended December 31, 2014	$59	$3	$—	$12	$50
Year ended December 31, 2013	$61	$5	$—	$7	$59