

AMGEN INC

Form 10-Q

October 31, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

OR

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

Commission file number 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

95-3540776

(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)

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

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

Smaller reporting company ☐ Emerging growth company ☐

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

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

As of October 24, 2018, the registrant had 637,219,244 shares of common stock, \$0.0001 par value, outstanding.

AMGEN INC.
INDEX

	Page No.
<u>PART I - FINANCIAL INFORMATION</u>	<u>1</u>
Item 1. <u>FINANCIAL STATEMENTS</u>	<u>1</u>
<u>CONDENSED CONSOLIDATED STATEMENTS OF INCOME</u>	<u>1</u>
<u>CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME</u>	<u>2</u>
<u>CONDENSED CONSOLIDATED BALANCE SHEETS</u>	<u>3</u>
<u>CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS</u>	<u>4</u>
<u>NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS</u>	<u>5</u>
Item 2. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>29</u>
Item 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>39</u>
Item 4. <u>CONTROLS AND PROCEDURES</u>	<u>39</u>
<u>PART II - OTHER INFORMATION</u>	<u>40</u>
Item 1. <u>LEGAL PROCEEDINGS</u>	<u>40</u>
Item 1A. <u>RISK FACTORS</u>	<u>40</u>
Item 2. <u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	<u>44</u>
Item 6. <u>EXHIBITS</u>	<u>44</u>
<u>INDEX TO EXHIBITS</u>	<u>45</u>
<u>SIGNATURES</u>	<u>50</u>

PART I — FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(In millions, except per-share data)

(Unaudited)

	Three months ended September 30, 2018		Nine months ended September 30, 2017	
Revenues:				
Product sales	\$5,510	\$5,453	\$16,532	\$16,226
Other revenues	394	320	985	821
Total revenues	5,904	5,773	17,517	17,047
Operating expenses:				
Cost of sales	1,037	990	3,005	3,010
Research and development	926	877	2,555	2,519
Selling, general and administrative	1,293	1,170	3,773	3,443
Other	325	297	303	347
Total operating expenses	3,581	3,334	9,636	9,319
Operating income	2,323	2,439	7,881	7,728
Interest expense, net	355	325	1,040	972
Interest and other income, net	126	267	519	627
Income before income taxes	2,094	2,381	7,360	7,383
Provision for income taxes	235	360	894	1,140
Net income	\$1,859	\$2,021	\$6,466	\$6,243
Earnings per share:				
Basic	\$2.88	\$2.78	\$9.67	\$8.52
Diluted	\$2.86	\$2.76	\$9.61	\$8.46
Shares used in calculation of earnings per share:				
Basic	645	728	669	733
Diluted	649	733	673	738
Dividends paid per share	\$1.32	\$1.15	\$3.96	\$3.45

See accompanying notes.

AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In millions)

(Unaudited)

	Three months ended September 30, 2018		2017		Nine months ended September 30, 2018		2017	
Net income	\$1,859		\$2,021		\$6,466		\$6,243	
Other comprehensive income (loss), net of reclassification adjustments and taxes:								
(Losses) gains on foreign currency translation	(71	)	41		(153	)	100	
Gains (losses) on cash flow hedges	41		(50	)	270		(324	)
Gains (losses) on available-for-sale securities	97		9		(237	)	247	
Other	(3	)	6		(1	)	5	
Other comprehensive income (loss), net of taxes	64		6		(121	)	28	
Comprehensive income	\$1,923		\$2,027		\$6,345		\$6,271	

See accompanying notes.

AMGEN INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In millions, except per-share data)

	September 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,956	\$ 3,800
Marketable securities	17,965	37,878
Trade receivables, net	3,441	3,237
Inventories	3,017	2,834
Other current assets	1,941	1,727
Total current assets	38,320	49,476
Property, plant and equipment, net	4,899	4,989
Intangible assets, net	7,782	8,609
Goodwill	14,684	14,761
Other assets	1,648	2,119
Total assets	\$ 67,333	\$ 79,954
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,042	\$ 1,352
Accrued liabilities	6,313	6,516
Current portion of long-term debt	5,077	1,152
Total current liabilities	12,432	9,020
Long-term debt	29,350	34,190
Long-term deferred tax liabilities	978	1,166
Long-term tax liabilities	8,832	9,099
Other noncurrent liabilities	1,392	1,238
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; \$0.0001 par value; 2,750.0 shares authorized; outstanding — 640.5 shares in 2018 and 722.2 shares in 2017	31,145	30,992
Accumulated deficit	(15,987)	(5,072)
Accumulated other comprehensive loss	(809)	(679)
Total stockholders' equity	14,349	25,241
Total liabilities and stockholders' equity	\$ 67,333	\$ 79,954

See accompanying notes.

AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)

(Unaudited)

	Nine months ended September 30, 2018 2017	
Cash flows from operating activities:		
Net income	\$6,466	\$6,243
Depreciation and amortization	1,456	1,506
Share-based compensation expense	224	244
Deferred income taxes	(294)	(379)
Other items, net	412	381
Changes in operating assets and liabilities, net of acquisition:		
Trade receivables, net	(234)	(229)
Inventories	(93)	(54)
Other assets	(110)	(110)
Accounts payable	(311)	(50)
Accrued income taxes, net	(384)	48
Long-term tax liabilities	204	314
Other liabilities	766	251
Net cash provided by operating activities	8,102	8,165
Cash flows from investing activities:		
Purchases of marketable securities	(12,617)	(26,661)
Proceeds from sales of marketable securities	28,059	18,580
Proceeds from maturities of marketable securities	3,881	4,765
Cash acquired in acquisition, net of cash paid	197	—
Purchases of property, plant and equipment	(513)	(511)
Other	(31)	(119)
Net cash provided by (used in) investing activities	18,976	(3,946)
Cash flows from financing activities:		
Net proceeds from issuance of debt	—	3,485
Repayment of debt	(500)	(4,405)
Net change in commercial paper	—	1,499
Repurchases of common stock	(15,670)	(2,371)
Dividends paid	(2,667)	(2,531)
Other	(85)	(137)
Net cash used in financing activities	(18,922)	(4,460)
Increase (decrease) in cash and cash equivalents	8,156	(241)
Cash and cash equivalents at beginning of period	3,800	3,241
Cash and cash equivalents at end of period	\$11,956	\$3,000

See accompanying notes.

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2018

(Unaudited)

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.

Basis of presentation

The financial information for the three and nine months ended September 30, 2018 and 2017, is unaudited but includes all adjustments (consisting of only normal, recurring adjustments unless otherwise indicated), which Amgen considers necessary for a fair presentation of its condensed consolidated results of operations for those periods. Interim results are not necessarily indicative of results for the full fiscal year.

The condensed consolidated financial statements should be read in conjunction with our consolidated financial statements and the notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2017, and with our condensed consolidated financial statements and the notes thereto contained in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018.

Principles of consolidation

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

Property, plant and equipment, net

Property, plant and equipment is recorded at historical cost, net of accumulated depreciation and amortization of \$8.0 billion and \$7.6 billion as of September 30, 2018 and December 31, 2017, respectively.

Revenues

Adoption of new revenue recognition standard

In May 2014, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards require an entity to recognize revenue when control of promised goods or services is transferred to the customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted this new standard as of January 1, 2018, by applying the modified-retrospective method to those contracts that were not completed as of that date.

The results for reporting periods beginning after January 1, 2018, are presented in accordance with the new standard, although comparative information has not been restated and continues to be reported under the accounting standards and policies in effect for those periods. See Note 1, Summary of significant accounting policies, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017.

Upon adoption, we recorded a net decrease of \$25 million to Accumulated deficit due to the cumulative impact of adopting the new standard—with the impact related primarily to the acceleration of deferred revenue, net of related deferred tax impact. The adoption of this new standard had an immaterial impact on our reported total revenues and operating income as compared to what reported amounts would have been under the prior standard, and we expect the impact of adoption in future periods to also be immaterial. Our accounting policies under the new standard were applied prospectively and are described below. See Note 4, Revenues.

Product sales and sales deductions

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

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

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

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

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

Other revenues

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

Arrangements with multiple-performance obligations

From time to time, we enter into arrangements for the research and development (R&D), manufacture and/or commercialization of products and product candidates. Such arrangements may require us to deliver various rights, services and/or goods, including (i) intellectual property rights or 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 nonrefundable, up-front license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing.

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

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

Other recently adopted pronouncements

In January 2016, the FASB issued a new accounting standard that amends the accounting and disclosures of financial instruments, including a provision requiring that equity investments (except for investments accounted for under the equity method of accounting) be measured at fair value, with changes in fair value recognized in current earnings.

With the exception of equity investments that were previously accounted for at cost, a modified-retrospective approach was used to reflect the cumulative effect of adoption as an adjustment to Accumulated deficit as of the beginning of the fiscal year. The new standard will be applied

prospectively to investments that were previously accounted for at cost. Upon adoption, on January 1, 2018, we recorded an immaterial adjustment to Accumulated deficit from Accumulated other comprehensive income (loss) (AOCI), which represented the net unrealized gain on all equity investments with a readily determinable fair value as of December 31, 2017. The impact that this new standard has on our Condensed Consolidated Statements of Income after adoption will depend on changes in fair values of equity securities in our portfolio in the future. See Note 8, Investments.

In October 2016, the FASB issued a new accounting standard that amends the income tax accounting guidance for intra-entity transfers of assets other than inventory. The new standard requires that entities recognize the income tax consequences of an intercompany transfer of an asset, other than inventory, in the period the transfer occurs. The current exception to defer the recognition of any tax impact on intercompany transfers of inventory until the inventory is sold to a third party remains unaffected. We adopted this standard as of January 1, 2018, and will apply it prospectively to any transaction occurring on or after the adoption date. The adoption of this standard did not have a material impact on our condensed consolidated financial statements, however the impact on our condensed consolidated financial statements in future periods will depend on the facts and circumstances of future transactions. In January 2017, the FASB issued a new accounting standard that changes the definition of a business to assist entities with the evaluation of when a set of assets acquired or disposed of should be considered a business. The new standard requires that an entity evaluate whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets; if so, the set of assets would not be considered a business. The new standard also requires that a business include at least one substantive process, and it narrows the definition of outputs. We adopted this standard as of January 1, 2018, and will apply it prospectively. Adoption of this new standard may result in more transactions being accounted for as asset acquisitions versus business combinations; however, the impact on our condensed consolidated financial statements in future periods will depend on the facts and circumstances of future transactions.

In August 2017, the FASB issued a new accounting standard that amends the accounting and reporting of hedging activities, which we elected to adopt early during the second quarter of 2018. Among its provisions, the new standard (i) eliminates the separate measurement and reporting of hedge ineffectiveness and (ii) permits an entity to recognize in earnings the initial fair value of an excluded component of a hedging instrument's fair value under a systematic and rational method over the life of the derivative instrument. In accordance with the transition provisions of the new standard, the separate measurement of ineffectiveness for our cash flow hedging instruments existing as of the date of adoption is required to be eliminated through a cumulative-effect adjustment to Accumulated deficit as of January 1, 2018, the beginning of the fiscal year. The ineffective portions of our cash flow hedges were not material to our previously issued condensed consolidated financial statements. In addition, certain provisions in the guidance require modifications to existing presentation and disclosure requirements on a prospective basis. The adoption of this standard did not have a material impact on our condensed consolidated financial statements. See Note 14, Derivative instruments.

In March 2018, the FASB issued a new accounting standard to incorporate U.S. Securities and Exchange Commission (SEC) Staff Accounting Bulletin No. 118 (SAB 118), which addresses accounting implications of major tax reform legislation Public Law No. 115-97, commonly referred to as the Tax Cuts and Jobs Act (the 2017 Tax Act), enacted on December 22, 2017. SAB 118 allows an entity to record provisional amounts during a measurement period not to extend beyond one year from the enactment date and was effective upon issuance. We continue to analyze the 2017 Tax Act and in certain areas have made reasonable estimates of the effects on our condensed consolidated financial statements and tax disclosures. See Note 5, Income taxes.

Other recent accounting pronouncements

In February 2016, the FASB issued a new accounting standard that amends the guidance for the accounting and disclosure of leases. This new standard requires that lessees recognize on the balance sheet the assets and liabilities that arise from leases, including leases classified as operating leases under current GAAP, and disclose qualitative and quantitative information about leasing arrangements. The new standard requires a modified-retrospective approach to adoption and is effective for interim and annual periods beginning on January 1, 2019, but may be adopted earlier. In July 2018, the FASB further amended this standard to allow for a new transition method that provides the option to use the effective date as the date of initial application. We intend to elect this alternative transition method and

therefore will not adjust comparative-period financial information. In addition, we intend to elect the package of practical expedients permitted under the transition guidance of the new standard to not reassess prior conclusions related to contracts that are or that contain leases, lease classification and initial direct costs. We expect to adopt this standard beginning in the first quarter of 2019. We do not expect that this standard will have a material impact on our Condensed Consolidated Statements of Income, but we do expect that upon adoption, it will have a material impact on our assets and liabilities on our Condensed Consolidated Balance Sheets. The primary effect of adoption will be the requirement to record right-of-use assets and the corresponding present value of lease obligation liabilities for current operating leases. The actual impact will depend on our lease portfolio at the time of adoption. In addition, the standard requires that we update the systems, processes and controls we use to track, record and account for our lease portfolio. We have selected a lease accounting information system, engaged third-party consultants and are progressing through system implementation. System readiness, including the implementation and functionality of software procured from third-party providers, is essential to enable preparation of the financial information required for this standard.

In June 2016, the FASB issued a new accounting standard that amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the “incurred loss” model with an “expected loss” model. Accordingly, these financial assets will be presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The new standard is effective for interim and annual periods beginning on January 1, 2020, but may be adopted earlier, beginning on January 1, 2019. With certain exceptions, adjustments are to be applied by using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. We are currently evaluating the impact that this new standard will have on our condensed consolidated financial statements.

2. Restructuring

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

We estimate that we will incur \$800 million to \$850 million of pretax charges in connection with our restructuring, including (i) separation and other headcount-related costs of \$540 million to \$560 million with respect to staff reductions and (ii) asset-related charges of \$260 million to \$290 million that consist primarily of asset impairments, accelerated depreciation and other related costs resulting from the consolidation of our worldwide facilities. Through September 30, 2018, we incurred \$547 million of separation costs and other headcount-related costs and \$251 million of net asset-related charges.

The amounts related to the restructuring recorded in the Condensed Consolidated Statements of Income during the three and nine months ended September 30, 2018 and 2017, were not significant. As of September 30, 2018, the total restructuring liability was not significant.

3. Business combinations

Kirin-Amgen, Inc.

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

K-A is a corporation that was established in 1984 as a 50-50 joint venture with Kirin to fund the global development of EPOGEN® (epoetin alfa). Over time, the scope of the collaboration was expanded to also include the products NEUPOGEN® (filgrastim), Neulasta® (pegfilgrastim), Aranesp® (darbepoetin alfa), Nplate® (romiplostim) and brodalumab. K-A held the intellectual property for each of these products and licensed the associated marketing rights in Asia to Kyowa Hakko Kirin (KHK), Kirin’s pharmaceutical subsidiary, and in most other territories to Amgen. In return, Amgen and KHK paid royalties to K-A, and K-A reimbursed Amgen and KHK’s R&D expenses. K-A had also given Johnson & Johnson (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.

Prior to the share acquisition date, we owned 50% of K-A and accounted for our interest in K-A by using the equity method of accounting, which included recording our share of K-A’s profits or losses in Selling, general and administrative expenses in the Condensed Consolidated Statements of Income. The carrying value of our equity method investment in K-A was \$570 million as of December 31, 2017, and is included in Other assets in the Condensed Consolidated Balance Sheets.

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

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

	Amount
Total cash paid to Kirin	\$780
Fair value of contingent consideration obligation	45
Loss on settlement of preexisting relationship	(168)
Total consideration transferred to acquire K-A	657

Fair value of Amgen's investment in K-A	825
Total acquisition date fair value	\$1,482

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

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

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

4. Revenues

Revenues by product and by geographic area

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

	Three months ended September 30,					
	2018			2017		
	US	ROW	Total	US	ROW	Total
Enbrel®	\$1,242	\$50	\$1,292	\$1,309	\$54	\$1,363
Neulasta®	897	154	1,051	977	146	1,123
Prolia®	354	178	532	298	166	464
Aranesp®	248	229	477	285	231	516
XGEVA®	323	110	433	282	105	387
Sensipar® / Mimpara®	330	79	409	373	84	457
EPOGEN®	252	—	252	264	—	264
Other products	614	450	1,064	509	370	879
Total product sales ⁽¹⁾	\$4,260	\$1,250	\$5,510	\$4,297	\$1,156	\$5,453
Other revenues			394			320
Total revenues ⁽²⁾			\$5,904			\$5,773

	Nine months ended September 30,			2017		
	2018			2017		
	US	ROW	Total	US	ROW	Total
Enbrel®	\$3,544	\$155	\$3,699	\$3,838	\$172	\$4,010
Neulasta®	2,854	452	3,306	2,962	458	3,420
Prolia®	1,070	566	1,636	903	491	1,394
Aranesp®	714	689	1,403	851	711	1,562
XGEVA®	994	336	1,330	872	312	1,184
Sensipar® / Mimpara®	1,069	257	1,326	1,052	253	1,305
EPOGEN®	746	—	746	826	—	826
Other products	1,783	1,303	3,086	1,474	1,051	2,525
Total product sales ⁽¹⁾	\$12,774	\$3,758	\$16,532	\$12,778	\$3,448	\$16,226
Other revenues			985			821
Total revenues ⁽²⁾			\$17,517			\$17,047

(1) Hedging gains and losses, which are included in product sales, were not material for the three and nine months ended September 30, 2018 and 2017.

(2) Prior-period amounts are not adjusted under the modified-retrospective method of adoption.

Financing and payment

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

For certain products or services and certain customer types, we may require payment before products are delivered or services are rendered to customers.

Optional exemptions

We do not disclose the value of unsatisfied performance obligations for (i) contracts with original expected lengths of one year or less or (ii) contracts for which we recognize revenue at the amount to which we have the right to invoice for the services performed.

5. Income taxes

The effective tax rates for the three and nine months ended September 30, 2018, were 11.2% and 12.1%, respectively, compared with 15.1% and 15.4%, respectively, for the corresponding periods of the prior year.

The decrease in our effective tax rate for the three and nine months ended September 30, 2018, was due primarily to the impacts of U.S. corporate tax reform.

On December 22, 2017, the United States enacted the 2017 Tax Act, which imposes a repatriation tax on accumulated earnings of foreign subsidiaries, implements a hybrid territorial tax system together with a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. In March 2018, the FASB issued a new accounting standard to incorporate SAB 118, which permits us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We continue to analyze the 2017 Tax Act and in certain areas have made reasonable estimates of the effects on our condensed consolidated financial statements and tax disclosures.

The 2017 Tax Act includes U.S. taxation on certain foreign earnings, referred to as Global Intangible Low-Taxed Income (foreign intangible income), effective January 1, 2018. The FASB allows an entity to make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as foreign intangible income in future years or provide for the tax expense related to the foreign intangible income as a period expense in the year it is incurred. We have recorded no provisional amount for deferred taxes on foreign intangible income because more time is needed to analyze the data in order to make an accounting policy election.

We consider our key estimates on the repatriation tax, the net deferred tax remeasurement, the impact on our unrealized tax benefits and the accounting policy election on temporary basis differences related to foreign intangible income to be incomplete

due to our continuing analysis of final year-end data and tax positions. We are still accumulating and processing data to update our underlying calculations, and we expect the U.S. Treasury and regulators may issue further guidance, among other things; therefore, our estimates may change during 2018. However, we expect to complete our analysis within the measurement period.

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

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely audited by the tax authorities in those jurisdictions. Significant disputes may arise with authorities involving issues of the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and the interpretation of the relevant facts. As previously disclosed, we received a Revenue Agent Report (RAR) from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. On November 29, 2017, we received a modified RAR that revised the IRS calculations but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution through the IRS administrative appeals process, which we believe will likely not be concluded within the next 12 months. Final resolution of the IRS audit could have a material impact on our results of operations and cash flows if not resolved favorably, however, we believe our income tax reserves are appropriately provided for all open tax years. We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009. We are currently under examination by a number of other state and foreign tax jurisdictions.

During the three and nine months ended September 30, 2018, the gross amounts of our unrecognized tax benefits (UTBs) increased \$70 million and \$225 million, respectively, as a result of tax positions taken during the current year. The UTB balance decreased by approximately \$50 million during the third quarter of 2018 due to a state tax audit settlement. Substantially all of the UTBs as of September 30, 2018, if recognized, would affect our effective tax rate.

6. Earnings per share

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

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

	Three months ended September 30, 2018		Nine months ended September 30, 2017	
Income (Numerator):				
Net income for basic and diluted EPS	\$1,859	\$2,021	\$6,466	\$6,243
Shares (Denominator):				
Weighted-average shares for basic EPS	645	728	669	733
Effect of dilutive securities	4	5	4	5
Weighted-average shares for diluted EPS	649	733	673	738
Basic EPS	\$2.88	\$2.78	\$9.67	\$8.52
Diluted EPS	\$2.86	\$2.76	\$9.61	\$8.46

For the three and nine months ended September 30, 2018 and 2017, the number of anti-dilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

7. Collaborations

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

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for nonrefundable up-front license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration arrangements are performed with no guarantee of either technological or commercial success, and each is unique in nature. See Note 1, Summary of significant accounting policies, for additional discussion of revenues recognized for these types of arrangements. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item, net of any payments due to or reimbursements due from our collaboration partners, with such reimbursements being recognized at the time the party becomes obligated to pay. The following describes a significant arrangement that had a material change since the filing of our Annual Report on Form 10-K for the year ended December 31, 2017.

Novartis AG

In April 2017, we expanded our existing migraine collaboration with Novartis AG (Novartis). In the United States, Amgen and Novartis jointly develop and collaborate on the commercialization of Aimovig® (erenumab-aooe).

Amgen, as the principal, recognizes product sales of Aimovig® in the United States, shares U.S. commercialization costs with Novartis and pays Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig® and other specified migraine programs. Novartis pays Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories and funds a portion of global R&D expenses. As a result of certain regulatory and commercial events, we received milestone payments from Novartis of \$147 million and \$295 million during the three and nine months ended September 30, 2018, respectively, and \$60 million during the three months ended September 30, 2017, which were recorded in Other revenues in the Condensed Consolidated Statements of Income. In addition, Novartis will make a payment to Amgen of up to \$100 million if certain commercial and expenditure thresholds are achieved with respect to Aimovig® in the United States. Amgen manufactures and supplies Aimovig® worldwide.

The migraine collaboration will continue for the commercial lives of the products unless terminated in accordance with its terms.

8. Investments

Available-for-sale investments

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

Types of securities as of September 30, 2018	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	\$ 2,710	\$ —	\$ (84)	\$ 2,626
U.S. Treasury bills	5,376	—	—	5,376
Other government-related debt securities:				
U.S.	112	—	(3)	109
Foreign and other	1,048	1	(41)	1,008
Corporate debt securities:				
Financial	2,786	—	(89)	2,697
Industrial	2,654	4	(80)	2,578
Other	594	—	(21)	573
Residential-mortgage-backed securities	1,524	—	(62)	1,462
Other mortgage- and asset-backed securities	490	—	(17)	473
Money market mutual funds	8,955	—	—	8,955
Other short-term interest-bearing securities	3,561	—	—	3,561
Total available-for-sale investments	\$ 29,810	\$ 5	\$ (397)	\$ 29,418

Types of securities as of December 31, 2017	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	\$ 8,313	\$ 1	\$ (72)	\$ 8,242
Other government-related debt securities:				
U.S.	225	—	(2)	223
Foreign and other	2,415	18	(11)	2,422
Corporate debt securities:				
Financial	10,089	17	(34)	10,072
Industrial	9,688	34	(52)	9,670
Other	1,393	3	(6)	1,390
Residential-mortgage-backed securities	2,198	—	(30)	2,168
Other mortgage- and asset-backed securities	2,312	—	(15)	2,297
Money market mutual funds	3,245	—	—	3,245
Other short-term interest-bearing securities	1,440	—	—	1,440
Total interest-bearing securities	41,318	73	(222)	41,169
Equity securities	135	14	—	149
Total available-for-sale investments	\$ 41,453	\$ 87	\$ (222)	\$ 41,318

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

Condensed Consolidated Balance Sheets locations	September 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 11,453	\$ 3,291
Marketable securities	17,965	37,878
Other assets	—	149
Total available-for-sale investments	\$ 29,418	\$ 41,318

Cash and cash equivalents in the above table excludes bank account cash of \$503 million and \$509 million as of September 30, 2018 and December 31, 2017, respectively. Other assets as of December 31, 2017, consisted of equity securities, which are no longer classified as available-for-sale.

As a result of the adoption of the new accounting standard related to the classification and measurement of financial instruments on January 1, 2018, equity investments (except for investments accounted for under the equity method of accounting) are now measured at fair value, with changes in fair value recognized in earnings. These investments were previously measured at fair value, with changes in fair value recognized in AOCI. Accordingly, these securities are no longer classified as available-for-sale and their presentation is not comparable to the presentation as of December 31, 2017. See Equity securities, discussed below, and Note 1, Summary of significant accounting policies.

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

Contractual maturities	September 30, 2018	December 31, 2017
Maturing in one year or less	\$ 17,943	\$ 6,733
Maturing after one year through three years	2,947	12,820
Maturing after three years through five years	5,585	13,836
Maturing after five years through ten years	1,008	3,263
Maturing after ten years	—	52
Mortgage- and asset-backed securities	1,935	4,465
Total interest-bearing securities	\$ 29,418	\$ 41,169

For the three months ended September 30, 2018 and 2017, realized gains on interest-bearing securities were \$5 million and \$26 million, respectively, and realized losses on interest-bearing securities were \$108 million and \$12 million, respectively. For the nine months ended September 30, 2018 and 2017, realized gains on interest-bearing securities were \$27 million and \$91 million, respectively, and realized losses on interest-bearing securities were \$379 million and \$183 million, respectively. Realized gains and losses on interest-bearing securities are recorded in Interest and other income, net, in the Condensed Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

The fair values and gross unrealized losses of available-for-sale investments in an unrealized loss position aggregated by type and length of time that the securities have been in a continuous loss position were as follows (in millions):

Types of securities as of September 30, 2018	Less than 12 months		12 months or more	
	Fair values	Unrealized losses	Fair values	Unrealized losses
U.S. Treasury notes	\$1,795	\$ (58)	\$831	\$ (26)
Other government-related debt securities:				
U.S.	43	(1)	66	(2)
Foreign and other	855	(38)	74	(3)
Corporate debt securities:				
Financial	2,262	(74)	397	(15)
Industrial	1,970	(68)	318	(12)
Other	533	(21)	13	—
Residential-mortgage-backed securities	673	(27)	782	(35)
Other mortgage- and asset-backed securities	135	(4)	337	(13)
Total	\$8,266	\$ (291)	\$2,818	\$ (106)
Types of securities as of December 31, 2017	Less than 12 months		12 months or more	
	Fair values	Unrealized losses	Fair values	Unrealized losses
U.S. Treasury notes	\$7,728	\$ (70)	\$195	\$ (2)
Other government-related debt securities:				
U.S.	188	(1)	34	(1)
Foreign and other	1,163	(9)	115	(2)
Corporate debt securities:				
Financial	5,928	(28)	462	(6)
Industrial	5,760	(43)	612	(9)
Other	868	(4)	117	(2)
Residential-mortgage-backed securities	1,838	(24)	276	(6)
Other mortgage- and asset-backed securities	1,777	(12)	250	(3)
Total	\$25,250	\$ (191)	\$2,061	\$ (31)

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

We review our available-for-sale investments for other-than-temporary declines in fair value below our cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. The evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below our cost basis and adverse conditions related specifically to the security, including any changes to the credit rating of the security, and the intent to sell or whether we will more likely than not be required to sell the security before recovery of its amortized cost basis. Our assessment of whether a security is

other-than-temporarily impaired could change in the future based on new developments or changes in assumptions related to that particular security. As of September 30, 2018, unrealized losses on available-for-sale investments were due primarily to higher interest rates on that date than at the time the securities were purchased. As of

September 30, 2018 and December 31, 2017, we believe the cost bases for our available-for-sale investments were recoverable in all material respects.

Equity securities

We held investments in equity securities with readily determinable fair values of \$217 million and \$149 million as of September 30, 2018 and December 31, 2017, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. As a result of the adoption of the new accounting standard related to the classification and measurement of financial instruments on January 1, 2018, equity investments (except for investments accounted for under the equity method of accounting) are now measured at fair value, with changes in fair value recognized in earnings. These investments were previously measured at fair value, with changes in fair value recognized in AOCI. Accordingly, these securities are no longer classified as available-for-sale and their presentation is not comparable to the presentation as of December 31, 2017. See Available-for-sale investments, discussed above, and Note 1, Summary of significant accounting policies. Gains and losses recognized on equity securities, including gains and losses recognized on sales, were not material for the three and nine months ended September 30, 2018 and 2017.

Limited partnership investments

We held limited partnership investments of \$292 million and \$213 million as of September 30, 2018 and December 31, 2017, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. These investments are measured by using the net asset values of the underlying investments as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of September 30, 2018, unfunded additional commitments to be made during the next several years for these investments were not material. Gains and losses recognized on our limited partnership investments were not material.

9. Inventories

Inventories consisted of the following (in millions):

	September 30, December 31,	
	2018	2017
Raw materials	\$ 288	\$ 232
Work in process	1,771	1,668
Finished goods	958	934
Total inventories	\$ 3,017	\$ 2,834

10. Goodwill and other intangible assets

Goodwill

The change in the carrying amount of goodwill was as follows (in millions):

	Nine months ended September 30, 2018
Beginning balance	\$ 14,761
Addition from K-A acquisition	6
Currency translation adjustment	(83)
Ending balance	\$ 14,684

Other intangible assets

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

	September 30, 2018			December 31, 2017		
	Gross carrying amounts	Accumulated amortization	Intangible assets, net	Gross carrying amounts	Accumulated amortization	Intangible assets, net
Finite-lived intangible assets:						
Developed-product-technology rights	\$ 12,586	\$ (7,312)	) \$ 5,274	\$ 12,589	\$ (6,796)	) \$ 5,793
Licensing rights	3,771	(1,921)	) 1,850	3,275	(1,601)	) 1,674
Marketing-related rights	1,285	(982)	) 303	1,319	(920)	) 399
R&D technology rights	1,159	(860)	) 299	1,161	(804)	) 357
Total finite-lived intangible assets	18,801	(11,075)	) 7,726	18,344	(10,121)	) 8,223
Indefinite-lived intangible assets:						
In-process research and development	56	—	56	386	—	386
Total other intangible assets	\$ 18,857	\$ (11,075)	) \$ 7,782	\$ 18,730	\$ (10,121)	) \$ 8,609

Developed-product-technology rights consist of rights related to marketed products acquired in business combinations. Licensing rights consist primarily of contractual rights acquired in business combinations to receive future milestone, royalty and profit sharing payments; capitalized payments to third parties for milestones related to regulatory approvals to commercialize products; and up-front payments associated with royalty obligations for marketed products. During the nine months ended September 30, 2018, licensing rights increased due to the K-A share acquisition. See Note 3, Business combinations. Marketing-related intangible assets consist primarily of rights related to the sale and distribution of marketed products. R&D technology rights consist of technology used in R&D with alternative future uses.

In-process research and development (IPR&D) consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. During the three months ended September 30, 2018, we discontinued the internal development of a non-key program, resulting in an impairment charge of \$330 million, which was recognized in Other operating expenses in the Condensed Consolidated Statements of Income and included in Other items, net, in the Condensed Consolidated Statements of Cash Flows.

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

During the three months ended September 30, 2018 and 2017, we recognized amortization expense associated with our finite-lived intangible assets of \$331 million and \$308 million, respectively. During the nine months ended September 30, 2018 and 2017, we recognized amortization expense associated with our finite-lived intangible assets of \$983 million and \$1.1 billion, respectively. Amortization of intangible assets is included primarily in Cost of sales in the Condensed Consolidated Statements of Income. The total estimated amortization expense for our finite-lived intangible assets for the remaining three months ending December 31, 2018, and the years ending December 31, 2019, 2020, 2021, 2022 and 2023, are \$0.3 billion, \$1.3 billion, \$1.2 billion, \$1.0 billion, \$0.9 billion and \$0.9 billion, respectively.

11. Financing arrangements

Our borrowings consisted of the following (in millions):

	September 30, December 31,	
	2018	2017
6.15% notes due 2018 (6.15% 2018 Notes)	\$ —	\$ 500
4.375% €550 million notes due 2018 (4.375% 2018 euro Notes)	648	653
5.70% notes due 2019 (5.70% 2019 Notes)	1,000	1,000
1.90% notes due 2019 (1.90% 2019 Notes)	700	700
Floating Rate Notes due 2019	550	550
2.20% notes due 2019 (2.20% 2019 Notes)	1,400	1,400
2.125% €675 million notes due 2019 (2.125% 2019 euro Notes)	783	810
4.50% notes due 2020 (4.50% 2020 Notes)	300	300
2.125% notes due 2020 (2.125% 2020 Notes)	750	750
Floating Rate Notes due 2020	300	300
2.20% notes due 2020 (2.20% 2020 Notes)	700	700
3.45% notes due 2020 (3.45% 2020 Notes)	900	900
4.10% notes due 2021 (4.10% 2021 Notes)	1,000	1,000
1.85% notes due 2021 (1.85% 2021 Notes)	750	750
3.875% notes due 2021 (3.875% 2021 Notes)	1,750	1,750
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	1,451	1,501
2.70% notes due 2022 (2.70% 2022 Notes)	500	500
2.65% notes due 2022 (2.65% 2022 Notes)	1,500	1,500
3.625% notes due 2022 (3.625% 2022 Notes)	750	750
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	713	719
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
3.125% notes due 2025 (3.125% 2025 Notes)	1,000	1,000
2.00% €750 million notes due 2026 (2.00% 2026 euro Notes)	870	901
2.60% notes due 2026 (2.60% 2026 Notes)	1,250	1,250
5.50% £475 million notes due 2026 (5.50% 2026 pound sterling Notes)	619	642
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	912	946
6.375% notes due 2037 (6.375% 2037 Notes)	552	552
6.90% notes due 2038 (6.90% 2038 Notes)	291	291
6.40% notes due 2039 (6.40% 2039 Notes)	466	466
5.75% notes due 2040 (5.75% 2040 Notes)	412	412
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	974	974
5.65% notes due 2042 (5.65% 2042 Notes)	487	487
5.375% notes due 2043 (5.375% 2043 Notes)	261	261
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
Other notes due 2097	100	100
Unamortized discounts, premiums, issuance costs and fair value adjustments, net	(1,168)	(929)
Total carrying value of debt	34,427	35,342
Less current portion	(5,077)	(1,152)
Total long-term debt	\$ 29,350	\$ 34,190

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

respectively.

17

12. Stockholders' equity

Stock repurchase program

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

	2018		2017	
	Shares	Dollars	Shares	Dollars
	*			
First quarter	56.4	\$10,787	3.4	\$555
Second quarter	18.2	3,190	6.2	1,006
Third quarter	8.7	1,713	4.4	769
Total stock repurchases	83.4	\$15,690	14.0	\$2,330

* Total shares may not add due to rounding.

In January 2018, the Board of Directors authorized an increase of \$10.0 billion available under our stock repurchase program. Repurchase activity for the three months ended March 31, 2018, included 52.1 million shares of our common stock acquired under a tender offer at an aggregate cost of \$10.0 billion. In April 2018, the Board of Directors increased the amount authorized under our stock repurchase program by an additional \$5.0 billion. As of September 30, 2018, \$3.7 billion remained available under our stock repurchase program.

Dividends

In July 2018, March 2018 and December 2017, the Board of Directors declared quarterly cash dividends of \$1.32 per share of common stock, which were paid in September 2018, June 2018 and March 2018, respectively. In October 2018, the Board of Directors declared a quarterly cash dividend of \$1.32 per share, which will be paid on December 7, 2018.

Accumulated other comprehensive income (loss)

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

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2017	\$ (529)	\$ (6)	\$ (144)	\$ —	\$(679)
Cumulative effect of change in accounting principle, net of tax ⁽¹⁾	—	—	(9)	—	(9)
Foreign currency translation adjustments	29	—	—	—	29
Unrealized gains (losses)	—	149	(482)	—	(333)
Reclassification adjustments to income	—	(130)	134	—	4
Other	—	—	—	2	2
Income taxes	—	(13)	5	—	(8)
Balance as of March 31, 2018	(500)	—	(496)	2	(994)
Foreign currency translation adjustments	(111)	—	—	—	(111)
Unrealized losses	—	(34)	(106)	—	(140)
Reclassification adjustments to income	—	318	115	—	433
Income taxes	—	(61)	—	—	(61)
Balance as of June 30, 2018	(611)	223	(487)	2	(873)
Foreign currency translation adjustments	(71)	—	—	—	(71)
Unrealized gains (losses)	—	19	(7)	—	12
Reclassification adjustments to income	—	33	103	—	136
Other	—	—	—	(3)	(3)
Income taxes	—	(11)	1	—	(10)
Balance as of September 30, 2018	\$ (682)	\$ 264	\$ (390)	\$ (1)	\$(809)

See Note 1, Summary of significant accounting policies, for additional information regarding the adoption on

⁽¹⁾ January 1, 2018, of the new accounting standard related to the classification and measurement of financial instruments and the related cumulative effect from the change in accounting principle.

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

		Three months ended September 30,		
Components of AOCI		2018	2017	Condensed Consolidated Statements of Income locations
Cash flow hedges:				
Foreign currency contract gains (losses)	\$3	\$ (2)		Product sales
Cross-currency swap contract (losses) gains	(36)	143		Interest and other income, net
Forward interest rate contract losses	—	(1)		Interest expense, net
	(33)	140		Income before income taxes
	7	(49)		Provision for income taxes
	\$(26)	\$91		Net income
Available-for-sale securities:				
Net realized (losses) gains	\$(103)	\$26		Interest and other income, net
	1	(5)		Provision for income taxes
	\$(102)	\$21		Net income
		Nine months ended September 30,		
Components of AOCI		2018	2017	Condensed Consolidated Statements of Income locations
Cash flow hedges:				
Foreign currency contract (losses) gains	\$(51)	\$88		Product sales
Cross-currency swap contract (losses) gains	(170)	514		Interest and other income, net
Forward interest rate contract losses	—	(1)		Interest expense, net
	(221)	601		Income before income taxes
	47	(213)		Provision for income taxes
	\$(174)	\$388		Net income
Available-for-sale securities:				
Net realized losses	\$(352)	\$(70)		Interest and other income, net
	3	(7)		Provision for income taxes
	\$(349)	\$(77)		Net income

13. Fair value measurement

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

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

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

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

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the

determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

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

Fair value measurement as of September 30, 2018, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Interest-bearing securities:				
U.S. Treasury notes	\$ 2,626	\$ —	\$ —	\$2,626
U.S. Treasury bills	5,376	—	—	5,376
Other government-related debt securities:				
U.S.	—	109	—	109
Foreign and other	—	1,008	—	1,008
Corporate debt securities:				
Financial	—	2,697	—	2,697
Industrial	—	2,578	—	2,578
Other	—	573	—	573
Residential-mortgage-backed securities	—	1,462	—	1,462
Other mortgage- and asset-backed securities	—	473	—	473
Money market mutual funds	8,955	—	—	8,955
Other short-term interest-bearing securities	—	3,561	—	3,561
Equity securities	217	—	—	217
Derivatives:				
Foreign currency contracts	—	121	—	121
Cross-currency swap contracts	—	261	—	261
Total assets	\$ 17,174	\$ 12,843	\$ —	\$30,017
Liabilities:				
Derivatives:				
Foreign currency contracts	\$ —	\$ 49	\$ —	\$49
Cross-currency swap contracts	—	306	—	306
Interest rate swap contracts	—	310	—	310
Contingent consideration obligations	—	—	66	66
Total liabilities	\$ —	\$ 665	\$ 66	\$731

Fair value measurement as of December 31, 2017, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Interest-bearing securities:				
U.S. Treasury notes	\$ 8,242	\$ —	\$ —	\$8,242
Other government-related debt securities:				
U.S.	—	223	—	223
Foreign and other	—	2,422	—	2,422
Corporate debt securities:				
Financial	—	10,072	—	10,072
Industrial	—	9,670	—	9,670
Other	—	1,390	—	1,390
Residential-mortgage-backed securities	—	2,168	—	2,168
Other mortgage- and asset-backed securities	—	2,297	—	2,297
Money market mutual funds	3,245	—	—	3,245
Other short-term interest-bearing securities	—	1,440	—	1,440
Equity securities	149	—	—	149
Derivatives:				
Foreign currency contracts	—	6	—	6
Cross-currency swap contracts	—	270	—	270
Interest rate swap contracts	—	10	—	10
Total assets	\$ 11,636	\$ 29,968	\$ —	\$41,604
Liabilities:				
Derivatives:				
Foreign currency contracts	\$ —	\$ 204	\$ —	\$204
Cross-currency swap contracts	—	220	—	220
Interest rate swap contracts	—	61	—	61
Contingent consideration obligations	—	—	69	69
Total liabilities	\$ —	\$ 485	\$ 69	\$554
Interest-bearing and equity securities				

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

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

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

observable, either directly or indirectly, to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment or default projections based on historical data; and other observable inputs.

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

Derivatives

All of our foreign currency forward and option derivative contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody’s or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, the London Interbank Offered Rate (LIBOR), swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. These inputs, where applicable, are at commonly quoted intervals. See Note 14, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody’s or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. See Note 14, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody’s or Fitch. We estimate the fair values of these contracts by using an income-based industry standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include LIBOR, swap rates and obligor credit default swap rates. See Note 14, Derivative instruments.

Contingent consideration obligations

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

Changes in the carrying amounts of contingent consideration obligations were as follows (in millions):

	Three months ended September 30, 2018		Nine months ended September 30, 2017	
Beginning balance	\$72	\$182	\$69	\$179
Addition from K-A acquisition	—	—	45	—
Net changes in valuations	(6)	(114)	(48)	(111)
Ending balance	\$66	\$68	\$66	\$68

As a result of our acquisition of BioVex Group, Inc., in 2011, we are obligated to pay its former shareholders additional consideration contingent upon achieving certain sales-related milestones with regard to IMLYGIC® (talimogene laherparepvec).

As a result of our acquisition of K-A in 2018, we are obligated to make single-digit royalty payments to Kirin contingent upon sales of brodalumab. See Note 3, Business combinations.

During 2017, we decided to discontinue the internal development of AMG 899, an IPR&D asset, and accordingly, reduced from \$116 million to zero the related contingent consideration liabilities. The remeasurement of these liabilities is included in Other items, net, in the Condensed Consolidated Statements of Cash Flows.

During the nine months ended September 30, 2018 and 2017, there were no transfers of assets or liabilities between fair value measurement levels. During the nine months ended September 30, 2018 and 2017, there were no material remeasurements

to fair values of assets and liabilities that are not measured at fair value on a recurring basis, except with respect to IPR&D assets discussed above, and in Note 10, Goodwill and other intangible assets.

Summary of the fair values of other financial instruments

Cash equivalents

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

Borrowings

We estimated the fair values of our borrowings by using Level 2 inputs. As of September 30, 2018 and December 31, 2017, the aggregate fair values of our borrowings were \$36.0 billion and \$38.6 billion, respectively, and the carrying values were \$34.4 billion and \$35.3 billion, respectively.

14. Derivative instruments

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

During the second quarter of 2018, we adopted early a new accounting standard that amends the accounting and reporting of hedging activities. Certain required disclosures have been made on a prospective basis in accordance with the guidance of the standard. See Note 1, Summary of significant accounting policies.

Cash flow hedges

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

As of September 30, 2018 and December 31, 2017, we had foreign currency forward contracts with notional amounts of \$4.5 billion and \$4.6 billion, respectively, and foreign currency option contracts with notional amounts of \$21 million and \$74 million, respectively. We have designated these foreign currency forward and foreign currency option contracts, which are primarily euro based, as cash flow hedges. Accordingly, we report the unrealized gains and losses on these contracts in AOCI in the Condensed Consolidated Balance Sheets, and we reclassify them to Product sales in the Condensed Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term debt denominated in foreign currencies, we enter into cross-currency swap contracts. Under the terms of such contracts, we paid euros, pounds sterling and Swiss francs and received U.S. dollars for the notional amounts at the inception of the contracts; and based on these notional amounts, we exchange interest payments at fixed rates over the lives of the contracts by paying U.S. dollars and receiving euros, pounds sterling and Swiss francs. In addition, we will pay U.S. dollars to and receive euros, pounds sterling and Swiss francs from the counterparties at the maturities of the contracts for these same notional amounts. The terms of these contracts correspond to the related hedged debt, thereby effectively converting the interest payments and principal repayment on the debt from euros, pounds sterling and Swiss francs to U.S. dollars. We have designated these cross-currency swap contracts as cash flow hedges. Accordingly, the unrealized gains and losses on these contracts are reported in AOCI in the Condensed Consolidated Balance Sheets and reclassified to Interest and other income, net, in the Condensed Consolidated Statements of Income in the same periods during which the hedged debt affects earnings.

The notional amounts and interest rates of our cross-currency swaps as of September 30, 2018, were as follows (notional amounts in millions):

Hedged notes	Foreign currency		U.S. dollars	
	Notional amounts	Interest rates	Notional amounts	Interest rates
2.125% 2019 euro Notes	€ 675	2.125 %	\$864	2.6 %
1.25% 2022 euro Notes	€ 1,250	1.25 %	\$1,388	3.2 %
0.41% 2023 Swiss franc Bonds	CHF700	0.41 %	\$704	3.4 %
2.00% 2026 euro Notes	€ 750	2.00 %	\$833	3.9 %
5.50% 2026 pound sterling Notes	£ 475	5.50 %	\$747	6.0 %
4.00% 2029 pound sterling Notes	£ 700	4.00 %	\$1,111	4.5 %

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Condensed Consolidated Balance Sheets and are amortized into Interest expense, net, in the Condensed Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the nine months ended September 30, 2018, and amounts expected to be recognized during the subsequent 12 months are not material.

The unrealized gains and losses recognized in AOCI for our derivative instruments designated as cash flow hedges were as follows (in millions):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Derivatives in cash flow hedging relationships	\$41	\$(110)	\$233	\$(360)
Foreign currency contracts	(22)	165	(99)	446
Cross-currency swap contracts	—	10	—	13
Forward interest rate contracts	\$19	\$65	\$134	\$99
Total unrealized gains				

The locations in the Condensed Consolidated Statements of Income and the gains and losses reclassified out of AOCI and into earnings for our derivative instruments designated as cash flow hedges were as follows (in millions):

	Condensed Consolidated Statements of Income locations	Three months ended September 30,		Nine months ended September 30,	
		2018	2017	2018	2017
Derivatives in cash flow hedging relationships					
Foreign currency contracts	Product sales	\$3	\$(2)	\$(51)	\$88
Cross-currency swap contracts	Interest and other income, net	(36)	143	(170)	514
Forward interest rate contracts	Interest expense, net	—	(1)	—	(1)
Total realized (losses) gains		\$(33)	\$140	\$(221)	\$601

No portions of our cash flow hedge contracts are excluded from the assessment of hedge effectiveness. As of September 30, 2018, the amount expected to be reclassified out of AOCI and into earnings during the next 12 months is \$124 million of net losses on our foreign currency and cross-currency swap contracts.

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified for and were designated as fair value hedges. The terms of these interest rate swap contracts correspond to the related

hedged debt and effectively converted fixed-rate coupons to floating-rate LIBOR-based coupons over the lives of the respective notes. As of September 30, 2018 and December 31, 2017, we had interest rate swap contracts with an aggregate notional amount of \$9.45 billion that hedge certain of our long-term debt issuances. The contracts have rates that range from three-month LIBOR plus 0.3% to three-month LIBOR plus 2.0%.

For interest rate swap contracts that qualify for and are designated as fair value hedges, we recognize in Interest expense, net, in the Condensed Consolidated Statements of Income the unrealized gain or loss on the derivative resulting from the change

in fair value during the period, as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. If a hedging relationship involving an interest rate swap contract is terminated, the gain or loss realized on contract termination is recorded as an adjustment to the carrying value of the debt and amortized into Interest expense, net, over the remaining life of the previously hedged debt.

Net unrealized gains and losses on our outstanding interest rate swap contracts were as follows (in millions):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Derivatives in fair value hedging relationships				
Net unrealized (losses) gains recognized for interest rate swap contracts	\$(44)	\$(17)	\$(259)	\$1
Net unrealized gains (losses) recognized for related hedged debt	\$44	\$17	\$259	\$(1)

The hedged liabilities and related cumulative-basis adjustments for fair value hedges of those liabilities were recorded in the Condensed Consolidated Balance Sheets as follows (in millions):

	Carrying amounts of hedged liabilities ⁽¹⁾		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities ⁽²⁾	
Condensed Consolidated Balance Sheet locations	September 30, 2018	December 31, 2017	September 30, 2018	December 31, 2017
Current portion of long-term debt	\$2,397	\$500	\$(2)	\$23
Long-term debt	\$7,859	\$10,516	\$(264)	\$(11)

Current portion of long-term debt includes \$1.0 billion and \$500 million of carrying value with discontinued hedging relationships as of September 30, 2018 and December 31, 2017, respectively. Long-term debt includes \$137 million and \$1.1 billion of carrying value with discontinued hedging relationships as of September 30, 2018 and December 31, 2017, respectively.

Current portion of long-term debt includes \$7 million and \$23 million of hedging adjustments on discontinued hedging relationships as of September 30, 2018 and December 31, 2017, respectively. Long-term debt includes \$37 million and \$40 million of hedging adjustments on discontinued hedging relationships as of September 30, 2018 and December 31, 2017, respectively.

The following table summarizes the amounts recorded in income and expense line items and the effects thereon from fair value and cash flow hedging, including discontinued hedging relationships (in millions):

	Three months ended September 30, 2018			Nine months ended September 30, 2018		
	Product sales	Interest and other income, net	Interest (expense), net	Product sales	Interest and other income, net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Condensed Consolidated Statements of Income	\$5,510	\$126	\$(355)	\$16,532	\$519	\$(1,040)

The effects of cash flow and fair value hedging:
Gains (losses) on cash flow hedging relationships reclassified out of AOCI:

Edgar Filing: AMGEN INC - Form 10-Q

Foreign currency contracts	\$3	\$ —	\$ —	\$(51)	\$ —	\$ —
Cross-currency swap contracts	\$ —	\$(36)	\$ —	\$ —	\$(170)	\$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:						
Hedged items ⁽¹⁾	\$ —	\$ —	\$ 48	\$ —	\$ —	\$ 278
Derivatives designated as hedging instruments	\$ —	\$ —	\$(44)	\$ —	\$ —	\$(259)

The amounts include benefits of \$4 million and \$19 million related to the amortization of the cumulative amount of ⁽¹⁾ fair value hedging adjustments included in the carrying amount of the hedged debt for discontinued hedging relationships for the three and nine months ended September 30, 2018, respectively.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. These exposures are hedged on a month-to-month basis. As of September 30, 2018 and December 31, 2017, the total notional amounts of these foreign currency forward contracts were \$243 million and \$757 million, respectively. The fair values of these derivatives as of September 30, 2018 and December 31, 2017, were not material.

The location in the Condensed Consolidated Statements of Income and the amounts of gains (losses) recognized in earnings for our derivative instruments not designated as hedging instruments were as follows (in millions):

		Three months ended September 30,	Nine months ended September 30,
Derivatives not designated as hedging instruments	Condensed Consolidated Statements of Income location	2018	2017
Foreign currency contracts	Interest and other income, net	\$ 11	\$(2)
		\$ 44	\$ 12

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

	Derivative assets Condensed Consolidated Balance Sheet locations	Fair values	Derivative liabilities Condensed Consolidated Balance Sheet locations	Fair values
September 30, 2018				
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	\$ 121	Accrued liabilities/ Other noncurrent liabilities	\$ 49
Cross-currency swap contracts	Other current assets/ Other assets	261	Accrued liabilities/ Other noncurrent liabilities	306
Interest rate swap contracts	Other current assets/ Other assets	—	Accrued liabilities/ Other noncurrent liabilities	310
Total derivatives designated as hedging instruments		\$ 382		\$ 665
December 31, 2017				
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	\$ 6	Accrued liabilities/ Other noncurrent liabilities	\$ 204
Cross-currency swap contracts	Other current assets/ Other assets	270	Accrued liabilities/ Other noncurrent liabilities	220
Interest rate swap contracts	Other current assets/ Other assets	10	Accrued liabilities/ Other noncurrent liabilities	61
Total derivatives designated as hedging instruments		\$ 286		\$ 485

Our derivative contracts that were in liability positions as of September 30, 2018, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our, or the surviving entity's, creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for

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

The cash flow effects of our derivative contracts are included within Net cash provided by operating activities in the Condensed Consolidated Statements of Cash Flows.

15. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See our Annual Report on Form 10-K for the year ended December 31, 2017, Part I, Item 1A. Risk Factors—Our business may be affected by litigation and government investigations. We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote; in Note 18, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017; and in Notes 14 and 15, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018, respectively.

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

Our legal proceedings involve various aspects of our business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing, in Note 18, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017, or in Notes 14 and 15, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018, respectively, plaintiffs seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process, which in complex proceedings of the sort we face often extend for several years. As a result, none of the matters pending against us described in this filing, in Note 18, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017, or in Notes 14 and 15, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018, respectively, have progressed sufficiently through discovery and/or the development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain recent developments concerning our legal proceedings and other matters are discussed below:

Sensipar® (cinacalcet) Litigation

Sensipar® Abbreviated New Drug Application (ANDA) Patent Litigation

On July 27, 2018, the U.S. District Court for the District of Delaware (the Delaware District Court) issued a trial order finding on the infringement claims and defenses in the Amgen Inc. v. Aurobindo Pharma Ltd. et al. consolidated lawsuit that Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, Zydus) infringe our U.S. Patent No. 9,375,405 (the '405 Patent) and that the following defendants do not infringe the '405 Patent: Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Piramal Healthcare UK Limited (Piramal); and Watson Laboratories, Inc., Actavis, Inc. and Actavis Pharma, Inc. (collectively, Watson).

On August 24, 2018, the Delaware District Court issued an order dismissing, without prejudice, the invalidity counterclaims of Amneal, Piramal, and Watson and entered judgment of non-infringement of the '405 Patent in favor of Amneal, Piramal and Watson. On September 20, 2018, Amgen filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court). On October 9, 2018, the Delaware District Court dismissed, without prejudice, the invalidity counterclaims of Zydus and entered judgment of infringement of the '405 Patent by Zydus in favor of Amgen, including an order that the effective date of the U.S. Food and Drug Administration (FDA) approval of Zydus's generic version of Sensipar® shall be no earlier than the expiry date of our '405 Patent. On October 11, 2018, Zydus filed a notice of appeal to the Federal Circuit Court and on October 24, 2018, the Federal Circuit

Court consolidated the appeals of Zydus and Amgen.

On September 7, 2018, Amgen filed a lawsuit in the Delaware District Court for infringement of the '405 Patent against Emcure Pharmaceuticals Ltd., Heritage Pharmaceuticals Inc., and Heritage Pharma Labs Inc.

As previously disclosed, Amgen filed lawsuits in the Delaware District Court and the U.S. District Court for the Middle District of North Carolina (the North Carolina District Court) each against Accord Healthcare, Inc. (Accord) and Intas Pharmaceuticals Ltd. (Intas) for infringement of the '405 Patent. On September 18, 2018, Accord responded to our lawsuit in the Delaware District Court by denying infringement of the '405 Patent and alleging that the patent is invalid. On September 20, 2018,

Intas was dismissed from the Delaware District Court lawsuit without prejudice by joint stipulation of the parties, and Amgen filed a notice voluntarily terminating the lawsuit filed in the North Carolina District Court.

Sensipar® Pediatric Exclusivity Litigation

On October 2, 2018, by agreement between Amgen and the FDA, the U.S. Court of Appeals for the District of Columbia Circuit dismissed Amgen's appeal of the final judgment that had been ordered by the U.S. District Court for the District of Columbia.

NEUPOGEN® (filgrastim)/ Neulasta® (pegfilgrastim) Litigation

Adello NEUPOGEN® Patent Litigation

On October 3, 2018, Amgen filed an amended complaint in the U.S. District Court for the District of New Jersey (the New Jersey District Court) adding defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc., to this patent infringement litigation and reducing the number of patents-in-suit from 17 to 4—specifically, U.S. Patent Nos. 8,940,878; 8,952,138; 9,643,997 (the '997 Patent); and 9,856,287 (the '287 Patent). On October 17, 2018, Adello Biologics, LLC (Adello) responded to the amended complaint, seeking judgment that our patents-in-suit are not infringed by Adello's biosimilar filgrastim product and that our patents are invalid.

Apotex NEUPOGEN®/Neulasta® Patent Litigation

On August 7, 2018, Amgen Inc. and Amgen Manufacturing, Ltd. (collectively, Amgen) filed a lawsuit in the U.S. District Court for the Southern District of Florida against Apotex Inc. and Apotex Corp. (collectively, Apotex) for infringement of the '287 Patent in accordance with the patent provisions of the Biologics Price Competition and Innovation Act. This lawsuit stems from Apotex's submissions of applications for FDA licensure of a pegfilgrastim product as biosimilar to Amgen's Neulasta® and a filgrastim product as biosimilar to Amgen's NEUPOGEN®. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Apotex from infringing the '287 Patent. On October 1, 2018, Apotex and Adello filed a petition in the United States Patent and Trademark Office requesting that the Patent Trial and Appeal Board institute post grant review proceedings on the '287 Patent.

Pfizer NEUPOGEN® Patent Litigation

On August 9, 2018, defendant Pfizer answered Amgen's complaint in this patent infringement litigation and included counterclaims seeking a declaratory judgment that Amgen's '997 Patent is not infringed by Pfizer's biosimilar filgrastim product and that our patent is invalid.

ENBREL (etanercept) Litigation

Sandoz ENBREL Patent Litigation

On September 10, 2018, the New Jersey District Court entered an order that the making, using, offering to sell or selling in the United States, or the importation into the United States by Sandoz Inc., Sandoz International GmbH, and Sandoz GmbH (collectively, Sandoz) of Sandoz's biosimilar etanercept product infringes U.S. Patent Nos. 8,063,182 and 8,163,522. The New Jersey District Court held a bench trial from September 11, 2018 to September 25, 2018 focusing on Sandoz's challenges to the validity of these patents. Closing arguments are scheduled for November 19, 2018.

Hospira EPOGEN® (epoetin alfa) Patent Litigation

Following a jury verdict finding our U.S. Patent No. 5,856,298 (the '298 Patent) valid and infringed by Hospira Inc. (Hospira) and awarding Amgen \$70 million in damages for such infringement, Hospira moved for judgment as a matter of law of noninfringement and invalidity of the '298 Patent or, in the alternative, for reduction of the damage award or a new trial on the '298 Patent. On August 27, 2018, the Delaware District Court denied Hospira's motion and final judgment was entered on September 11, 2018. On October 3, 2018, Hospira filed a notice of appeal to the Federal Circuit Court and on October 15, 2018, Amgen filed a cross-appeal.

MVASI™(bevacizumab-awwb) Patent Litigation

On August 31, 2018, plaintiffs Genentech and City of Hope reduced the number of asserted patents in this patent infringement litigation pending against Amgen from 26 to 8 in accordance with the scheduling order issued by the Delaware District Court. The jury trial has been rescheduled to begin on July 13, 2020.

KANJINTI™(trastuzumab) Patent Litigation

On August 23, 2018, plaintiffs Genentech and City of Hope moved to dismiss Amgen's unenforceability counterclaims and affirmative defense in this patent infringement litigation pending against Amgen.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations (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 Annual Report on Form 10-K for the year ended December 31, 2017, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018. Our results of operations discussed in MD&A are presented in conformity with GAAP. Amgen operates in one business segment: human therapeutics.

Therefore, our results of operations are discussed on a consolidated basis.

Forward-looking statements

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

Overview

Amgen is a highly focused biotechnology company committed to unlocking the potential of biology for patients suffering from serious illness. 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.

Currently, we market in six therapeutic areas: cardiovascular, oncology/hematology, neuroscience, inflammation, nephrology and bone health. Our principal products—those with the most significant commercial sales—are ENBREL®, Neulasta®, Prolia® (denosumab), Aranesp®, XGEVA® (denosumab), Sensipar®/Mimpara® and EPOGEN®. We also market a number of other products, including KYPROLIS®, Nplate®, Vectibix® (panitumumab), Repatha®, NEUPOGEN®, Parsabiv® (etelcalcetide), BLINCYTO® (blinatumomab), Aimovig®, IMLYGIC®, Corlanor® (ivabradine), KANJINTI™ and AMGEVITA™ (biosimilar adalimumab).

Significant developments

Following is a summary of selected significant developments affecting our business that have occurred since the filing of our Quarterly Report on Form 10-Q for the period ended June 30, 2018. For additional developments or for a more comprehensive discussion of certain developments discussed below, see our Annual Report on Form 10-K for the year ended December 31, 2017, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018.

Products/Pipeline

Cardiovascular

Repatha® (evolocumab)

In October 2018, we introduced a set of new National Drug Codes (NDCs) to make Repatha® available at the lower list price of \$5,850 per year to address affordability for patients, particularly those on Medicare.

Inflammation

Tezepelumab

In September 2018, we announced that the FDA granted Breakthrough Therapy Designation for tezepelumab in patients with severe asthma without an eosinophilic phenotype. Tezepelumab is being jointly developed in collaboration with AstraZeneca plc.

Oncology/Hematology

BLINCYTO®

In August 2018, we announced that the European Commission approved an expanded indication for BLINCYTO® as monotherapy for the treatment of pediatric patients aged one year or older with Philadelphia chromosome-negative CD19 positive B-cell precursor acute lymphoblastic leukemia (ALL), which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation.

KYPROLIS®

In October 2018, we announced that the FDA approved the supplemental New Drug Application to expand the Prescribing Information for KYPROLIS® to include a once-weekly dosing option in combination with dexamethasone for patients with relapsed or refractory multiple myeloma. The approval is based on data from the phase 3 ARROW (Randomized, Open-label, Phase 3 Study in Subjects with Relapsed and Refractory Multiple Myeloma Receiving Carfilzomib in Combination with Dexamethasone, Comparing Once-Weekly versus Twice-Weekly Carfilzomib Dosing) study, which demonstrated that KYPROLIS® administered once-weekly at 70 mg/m² with dexamethasone achieved superior progression-free survival and overall response rates, with a comparable safety profile, versus twice-weekly KYPROLIS® administered at a dose of 27 mg/m² in combination with dexamethasone.

Biosimilars

AMGEVITA™

In October 2018, we announced that AMGEVITA™ began launching in markets across Europe beginning in October 2018.

Selected financial information

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

	Three months ended			Nine months ended			
	September 30,			September 30,			
	2018	2017	Change	2018	2017	Change	
Product sales							
U.S.	\$4,260	\$4,297	(1)%	\$12,774	\$12,778	—	%
ROW	1,250	1,156	8 %	3,758	3,448	9 %	
Total product sales	5,510	5,453	1 %	16,532	16,226	2 %	
Other revenues	394	320	23 %	985	821	20 %	
Total revenues	\$5,904	\$5,773	2 %	\$17,517	\$17,047	3 %	
Operating expenses	\$3,581	\$3,334	7 %	\$9,636	\$9,319	3 %	
Operating income	\$2,323	\$2,439	(5)%	\$7,881	\$7,728	2 %	
Net income	\$1,859	\$2,021	(8)%	\$6,466	\$6,243	4 %	
Diluted EPS	\$2.86	\$2.76	4 %	\$9.61	\$8.46	14 %	
Diluted shares	649	733	(11)%	673	738	(9)%	

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

Total product sales increased for the three and nine months ended September 30, 2018, driven primarily by higher unit demand, offset partially by a decline in net selling price.

Other revenues increased for the three months ended September 30, 2018, driven primarily by higher milestone payments. Other revenues increased for the nine months ended September 30, 2018, driven primarily by higher milestone payments and royalties.

Operating expenses increased for the three months ended September 30, 2018, driven primarily by higher manufacturing costs and investments in product launches and marketed product support. Operating expenses increased for the nine months ended September 30, 2018, driven primarily by higher investments in product launches and marketed product support. All expense categories continued to benefit from our transformation and process improvement efforts, which enabled investment in newer and recently launched products.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is offset partially by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material for the three and nine months ended September 30, 2018 and 2017.

Results of operations

Product sales

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

	Three months ended September 30,			Nine months ended September 30,		
	2018	2017	Change	2018	2017	Change
ENBREL	\$1,292	\$1,363	(5)%	\$3,699	\$4,010	(8)%
Neulasta®	1,051	1,123	(6)%	3,306	3,420	(3)%
Prolia®	532	464	15 %	1,636	1,394	17 %
Aranesp®	477	516	(8)%	1,403	1,562	(10)%
XGEVA®	433	387	12 %	1,330	1,184	12 %
Sensipar®/Mimpara®	409	457	(11)%	1,326	1,305	2 %
EPOGEN®	252	264	(5)%	746	826	(10)%
Other products	1,064	879	21 %	3,086	2,525	22 %
Total product sales	\$5,510	\$5,453	1 %	\$16,532	\$16,226	2 %

Future sales of our products will depend, in part, on the factors discussed below and in the following sections of our Annual Report on Form 10-K for the year ended December 31, 2017: (i) Item 1. Business—Marketing, Distribution and Selected Marketed Products; (ii) Item 1A. Risk Factors; and (iii) Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Overview, and Results of Operations—Product Sales, as well as in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018, in (i) Part I, Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Product Sales; and (ii) Part II, Item 1A. Risk Factors.

ENBREL

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

	Three months ended September 30,			Nine months ended September 30,		
	2018	2017	Change	2018	2017	Change
ENBREL — U.S.	\$1,242	\$1,309	(5)%	\$3,544	\$3,838	(8)%
ENBREL — Canada	50	54	(7)%	155	172	(10)%
Total ENBREL	\$1,292	\$1,363	(5)%	\$3,699	\$4,010	(8)%

The decrease in ENBREL sales for the three months ended September 30, 2018, was driven primarily by lower unit demand and, to a lesser extent, lower net selling price, offset partially by favorable changes in accounting estimates. The decrease in ENBREL sales for the nine months ended September 30, 2018, was driven primarily by lower unit demand.

For 2018, we expect the trend of lower unit demand to continue. In addition, we continue to expect the 2018 net selling price to decline slightly compared with 2017.

Multiple companies are developing proposed biosimilar versions of ENBREL, one of which was approved by the FDA in 2016. For a discussion of ongoing patent litigations with companies that are developing proposed biosimilar versions of ENBREL, see Note 15, Contingencies and commitments, to the condensed consolidated financial statements; Note 18, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017; and Notes 14 and 15, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018, respectively.

Neulasta®

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

	Three months ended			Nine months ended		
	September 30, 2018			September 30, 2017		
	2018	2017	Change	2018	2017	Change
Neulasta®— U.S.	\$897	\$977	(8)%	\$2,854	\$2,962	(4)%
Neulasta®— ROW	54	146	5 %	452	458	(1)%
Total Neulasta®	\$1,051	\$1,123	(6)%	\$3,306	\$3,420	(3)%

The decrease in global Neulasta® sales for the three months ended September 30, 2018, was driven primarily by lower net selling price, lower unit demand and favorable prior-period changes in accounting estimates. The decrease in global Neulasta® sales for the nine months ended September 30, 2018, was driven primarily by lower unit demand and unfavorable changes in accounting estimates, offset partially by an increase in net selling price.

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

Our final material U.S. patent for Neulasta® expired in October 2015. Therefore, we face competition in the United States, which over time may have a material adverse impact on future sales of Neulasta®. A biosimilar version of Neulasta® was approved in the second quarter of 2018 and launched in July 2018. One company has a Biosimilar User Fee Action date for its biosimilar version of Neulasta® in the fourth quarter of 2018 and other biosimilar versions of Neulasta® may also receive approval in the near future. For a discussion of ongoing patent litigations with these and other companies that are developing proposed biosimilar versions of Neulasta®, see Note 15, Contingencies and commitments, to the condensed consolidated financial statements; Note 18, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017; and Notes 14 and 15, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018, respectively.

In addition, supplementary protection certificates issued by certain countries, including France, Germany, Italy, Spain and the United Kingdom, that are related to our European patent for Neulasta® expired in August 2017.

Prolia®

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

	Three months ended			Nine months ended		
	September 30, 2018			September 30, 2017		
	2018	2017	Change	2018	2017	Change
Prolia® — U.S.	\$354	\$298	19 %	\$1,070	\$903	18 %
Prolia® — ROW	78	166	7 %	566	491	15 %
Total Prolia®	\$532	\$464	15 %	\$1,636	\$1,394	17 %

The increases in global Prolia® sales for the three and nine months ended September 30, 2018, were driven primarily by higher unit demand. Prolia®, which has a six-month dosing interval, has exhibited a historical sales pattern, with the first and third quarters of a year representing lower sales than the second and fourth quarters of a year.

Aranesp®

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

	Three months ended September 30,			Nine months ended September 30,		
	2018	2017	Change	2018	2017	Change
Aranesp® — U.S.	\$248	\$285	(13)%	\$714	\$851	(16)%
Aranesp® — ROW	\$29	\$231	(1)%	\$689	\$711	(3)%
Total Aranesp®	\$477	\$516	(8)%	\$1,403	\$1,562	(10)%

The decreases in global Aranesp® sales for the three and nine months ended September 30, 2018, were driven primarily by the impact of competition on unit demand.

Aranesp® faces competition from a long-acting product. We expect to face competition from biosimilar versions of EPOGEN®. A biosimilar version of EPOGEN® was approved in the second quarter of 2018 and may launch. Other biosimilar versions of EPOGEN® may also receive approval.

XGEVA®

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

	Three months ended September 30,			Nine months ended September 30,		
	2018	2017	Change	2018	2017	Change
XGEVA® — U.S.	\$323	\$282	15 %	\$994	\$872	14 %
XGEVA® — ROW	\$10	\$105	5 %	\$336	\$312	8 %
Total XGEVA®	\$433	\$387	12 %	\$1,330	\$1,184	12 %

The increases in global XGEVA® sales for the three and nine months ended September 30, 2018, were driven primarily by higher unit demand.

Sensipar®/Mimpara®

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

	Three months ended September 30,			Nine months ended September 30,		
	2018	2017	Change	2018	2017	Change
Sensipar® — U.S.	\$330	\$373	(12)%	\$1,069	\$1,052	2 %
Sensipar®/Mimpara® — ROW	\$9	\$84	(6)%	\$257	\$253	2 %
Total Sensipar®/Mimpara®	\$409	\$457	(11)%	\$1,326	\$1,305	2 %

The decrease in global Sensipar®/Mimpara® sales for the three months ended September 30, 2018, was driven primarily by lower unit demand, which was due to continued adoption of Parsabiv® in the United States. The increase in global Sensipar®/Mimpara® sales for the nine months ended September 30, 2018, was driven primarily by an increase in net selling price.

Our U.S. composition of matter patent related to Sensipar®, a small molecule, expired in March 2018. We are involved in patent litigations with a number of companies seeking to market generic versions of Sensipar®. See Note 15, Contingencies and commitments, to the condensed consolidated financial statements; Note 18, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017; and Notes 14 and 15, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018,

respectively. The forward looking outlook for Sensipar® is uncertain as generic competitors may enter the market at risk at any time.

EPOGEN®

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

	Three months ended September 30, 2018	2017	Change	Nine months ended September 30, 2018	2017	Change
EPOGEN® — U.S.	\$252	\$264	(5)%	\$746	\$826	(10)%

The decrease in EPOGEN® sales for the three months ended September 30, 2018, was driven primarily by a decrease in net selling price due to contractual terms negotiated with DaVita Inc. The decrease in EPOGEN® sales for the nine months ended September 30, 2018, was driven primarily by a decrease in net selling price and, to a lesser extent, lower unit demand.

Our final material U.S. patent for EPOGEN® expired in May 2015. We face competition in the United States, which has had and will continue to have a material adverse impact on sales of EPOGEN®. Multiple companies are developing proposed biosimilar versions of EPOGEN®. A biosimilar version of EPOGEN® was approved in the second quarter of 2018 and may launch. Other biosimilar versions of EPOGEN® may also receive approval. For a discussion of ongoing patent litigation with one of these companies, see Note 15, Contingencies and commitments, to the condensed consolidated financial statements and Note 18, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017.

Other products

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

	Three months ended September 30, 2018			Nine months ended September 30, 2018				
	2018	2017	Change	2018	2017	Change		
KYPROLIS® — U.S.	\$142	\$135	5 %	\$430	\$412	4 %		
KYPROLIS® — ROW	90	72	25 %	287	196	46 %		
Nplate® — U.S.	107	96	11 %	326	292	12 %		
Nplate® — ROW	70	63	11 %	209	185	13 %		
Vectibix® — U.S.	71	65	9 %	214	188	14 %		
Vectibix® — ROW	110	103	7 %	309	295	5 %		
Repatha® — U.S.	72	62	16 %	254	155	64 %		
Repatha® — ROW	48	27	78 %	137	66	*		
NEUPOGEN® — U.S.	52	96	(46)%	180	287	(37)%		
NEUPOGEN® — ROW	33	42	(21)%	110	136	(19)%		
Parsabiv® — U.S.	92	—	*	194	—	*		
Parsabiv® — ROW	10	2	*	22	2	*		
BLINCYTO® — U.S.	33	34	(3)%	97	85	14 %		
BLINCYTO® — ROW	25	18	39 %	70	44	59 %		
Aimovig® — U.S.	22	—	*	24	—	*		
Other — U.S.	23	21	10 %	64	55	16 %		
Other — ROW	64	43	49 %	159	127	25 %		
Total other products	\$1,064	\$879	21 %	\$3,086	\$2,525	22 %		
Total U.S. — other products	\$614	\$509	21 %	\$1,783	\$1,474	21 %		
Total ROW — other products	\$450	\$370	22 %	\$1,303	\$1,051	24 %		
Total other products	\$1,064	\$879	21 %	\$3,086	\$2,525	22 %		

* Change in excess of 100%.

Operating expenses

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

	Three months ended September 30,				Nine months ended September 30,			
	2018	2017	Change		2018	2017	Change	
Operating expenses:								
Cost of sales	\$1,037	\$990	5	%	\$3,005	\$3,010	—	%
% of product sales	18.8	% 18.2	%		18.2	% 18.6	%	
% of total revenues	17.6	% 17.1	%		17.2	% 17.7	%	
Research and development	\$926	\$877	6	%	\$2,555	\$2,519	1	%
% of product sales	16.8	% 16.1	%		15.5	% 15.5	%	
% of total revenues	15.7	% 15.2	%		14.6	% 14.8	%	
Selling, general and administrative	\$1,293	\$1,170	11	%	\$3,773	\$3,443	10	%
% of product sales	23.5	% 21.5	%		22.8	% 21.2	%	
% of total revenues	21.9	% 20.3	%		21.5	% 20.2	%	
Other	\$325	\$297	9	%	\$303	\$347	(13)	%

Transformation and process improvements

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

The transformation includes a restructuring plan that we estimate will result in pretax accounting charges in the range of \$800 million to \$850 million. As of September 30, 2018, restructuring costs incurred to date were \$798 million. The charges that were recorded related to the restructuring during the three and nine months ended September 30, 2018, were not significant. Since 2014, we have realized approximately \$1.6 billion of transformation and process improvement savings. Net savings have not been significant as savings were reinvested in product launches, clinical programs and external business development.

Cost of sales

Cost of sales increased to 17.6% of total revenues for the three months ended September 30, 2018, driven primarily by higher manufacturing costs and higher acquisition-related amortization of intangible assets, offset partially by lower royalty costs and the favorable comparison to Hurricane Maria-related charges in the third quarter of 2017.

Cost of sales decreased to 17.2% of total revenues for the nine months ended September 30, 2018, driven primarily by lower royalty costs and a decrease in acquisition-related amortization of intangible assets, offset partially by higher manufacturing costs.

Research and development

R&D expenses increased for the three months ended September 30, 2018, driven primarily by increases in later-stage clinical programs of \$59 million and Discovery Research and Translation Sciences of \$35 million, offset partially by a decrease in marketed-product support of \$45 million.

R&D expenses increased for the nine months ended September 30, 2018, driven primarily by increases in later-stage clinical programs of \$77 million and Discovery Research and Translation Sciences of \$82 million, offset partially by a decrease in marketed-product support of \$123 million.

Selling, general and administrative

The increases in Selling, general and administrative expenses for the three and nine months ended September 30, 2018, were driven primarily by investments in product launches and marketed product support.

Other

Other operating expenses for the three months ended September 30, 2018, increased due primarily to higher impairment-related charges associated with intangible assets acquired in business combinations. Other operating expenses for the nine months

ended September 30, 2018, decreased due primarily to lower restructuring charges and favorable changes in fair values of contingent consideration, offset partially by higher impairment-related charges associated with intangible assets acquired in business combinations.

Nonoperating expense/income and income taxes

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

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Interest expense, net	\$355	\$325	\$1,040	\$972
Interest and other income, net	\$126	\$267	\$519	\$627
Provision for income taxes	\$235	\$360	\$894	\$1,140
Effective tax rate	11.2 %	15.1 %	12.1 %	15.4 %

Interest expense, net

The increase in Interest expense, net, for the three and nine months ended September 30, 2018, was due primarily to the impact of rising interest rates on variable-rate debt.

Interest and other income, net

The decrease in Interest and other income, net, for the three months ended September 30, 2018, was due primarily to higher investment losses and reduced returns as a result of the liquidation of a portion of our portfolio. The decrease in Interest and other income, net, for the nine months ended September 30, 2018, was due primarily to higher investment losses and reduced returns as a result of the liquidation of a portion of our portfolio, offset partially by gains on our equity investments and a net gain recognized in connection with our acquisition of K-A in the first quarter of 2018. See Note 3, Business combinations, to the condensed consolidated financial statements.

Income taxes

The decrease in our effective tax rate for the three and nine months ended September 30, 2018, was due primarily to the impacts of U.S. corporate tax reform.

On December 22, 2017, the United States enacted the 2017 Tax Act, which imposes a repatriation tax on accumulated earnings of foreign subsidiaries, implements a hybrid territorial tax system together with a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. In March 2018, the FASB issued a new accounting standard to incorporate SAB 118, which permits us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We continue to analyze the 2017 Tax Act and in certain areas have made reasonable estimates of the effects on our condensed consolidated financial statements and tax disclosures.

The 2017 Tax Act includes U.S. taxation on foreign intangible income, effective January 1, 2018. The FASB allows an entity to make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as foreign intangible income in future years or provide for the tax expense related to the foreign intangible income as a period expense in the year it is incurred. We have recorded no provisional amount for deferred taxes on foreign intangible income because more time is needed to analyze the data in order to make an accounting policy election.

We consider our key estimates on the repatriation tax, the net deferred tax remeasurement, the impact on our unrealized tax benefits and the accounting policy election on temporary basis differences related to foreign intangible income to be incomplete due to our continuing analysis of final year-end data and tax positions. We are still accumulating and processing data to update our underlying calculations, and we expect the U.S. Treasury and regulators may issue further guidance, among other things; therefore, our estimates may change during 2018. However, we expect to complete our analysis within the measurement period.

As previously disclosed, we received an RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. On November 29, 2017, we received a modified RAR that revised the IRS calculations but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution through the IRS administrative appeals process, which we believe will likely not be concluded

within the next 12 months. Final resolution of the IRS audit could have a material impact on our results of operations and cash flows if not resolved favorably, however, we believe our income tax reserves are appropriately provided for all open tax years. See Note 5, Income taxes, to the condensed consolidated financial statements for further discussion.

Financial condition, liquidity and capital resources

Selected financial data was as follows (in millions):

	September 30, 2018	December 31, 2017
Cash, cash equivalents and marketable securities	\$ 29,921	\$ 41,678
Total assets	\$ 67,333	\$ 79,954
Current portion of long-term debt	\$ 5,077	\$ 1,152
Long-term debt	\$ 29,350	\$ 34,190
Stockholders' equity	\$ 14,349	\$ 25,241

Cash, cash equivalents and marketable securities

We have global access to our \$29.9 billion balance of cash, cash equivalents and marketable securities, as we no longer reinvest our undistributed foreign earnings indefinitely outside the United States. As a result of the 2017 Tax Act, we recorded a repatriation tax liability on undistributed earnings generated from operations in foreign tax jurisdictions estimated at \$7.3 billion, which will be paid over eight years. The first annual payment was made in April 2018.

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

Capital allocation

Consistent with the objective to optimize our capital structure, we seek to deploy our accumulated cash balances in an efficient manner, and we consider several alternatives such as share repurchases, payment of cash dividends, repayment of debt and strategic transactions that expand our portfolio of products in areas of therapeutic interest. We intend to continue to invest in our business and return capital to stockholders through the payment of cash dividends and stock repurchases reflecting our confidence in the future cash flows of our business. The timing and amount of future dividends and stock repurchases will vary based on a number of factors, including future capital requirements for strategic transactions, the availability of financing on acceptable terms, debt service requirements, our credit rating, changes to applicable tax laws or corporate laws, changes to our business model and periodic determination by our Board of Directors that cash dividends and/or stock repurchases are in the best interests of stockholders and are in compliance with applicable laws and agreements of the Company. In addition, the timing and amount of stock repurchases may also be affected by stock price and blackout periods during which we are restricted from repurchasing stock. The manner of stock repurchases may include private block purchases, tender offers and market transactions.

In July 2018, March 2018 and December 2017, the Board of Directors declared quarterly cash dividends of \$1.32 per share of common stock, which were paid on September 7, 2018, June 8, 2018 and March 8, 2018, respectively. In October 2018, the Board of Directors declared a quarterly cash dividend of \$1.32 per share of common stock, which will be paid on December 7, 2018.

We have also returned capital to stockholders through our stock repurchase program. During the nine months ended September 30, 2018, we repurchased \$15.7 billion of our stock, which included 52.1 million shares of common stock repurchased through a \$10.0 billion tender offer. In April 2018, our Board of Directors increased the amount authorized under our stock repurchase program by an additional \$5.0 billion. As of September 30, 2018, \$3.7 billion remained available under the Board of Directors-approved stock repurchase program.

As a result of stock repurchases, including our recent tender offer, and quarterly dividend payments, we have an accumulated deficit as of September 30, 2018 and December 31, 2017. Our accumulated deficit is not expected to affect our future ability to operate, repurchase stock, pay dividends or repay our debt given our continuing profitability and strong financial position.

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

and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt

markets and equity markets. See our Annual Report on Form 10-K for the year ended December 31, 2017, Part I, Item 1A. Risk Factors—Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which was modified during the three months ended March 31, 2018. The modified covenant requires that we maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the amended credit agreement. We were in compliance with all applicable covenants under these arrangements as of September 30, 2018.

Cash flows

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

	Nine months ended September 30,	
	2018	2017
Net cash provided by operating activities	\$8,102	\$8,165
Net cash provided by (used in) investing activities	\$18,976	\$(3,946)
Net cash used in financing activities	\$(18,922)	\$(4,460)

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 during the nine months ended September 30, 2018, decreased compared with the same period in the prior year due primarily to higher cash taxes resulting from the first installment payment of repatriation tax arising from the 2017 Tax Act, net of reduced payments on our ongoing income tax liability, and the timing of payments to vendors, substantially offset by higher sales incentives and allowances to be paid to customers.

Investing

Cash provided by investing activities during the nine months ended September 30, 2018, was due primarily to net activity related to marketable securities of \$19.3 billion, offset partially by capital expenditures of \$513 million. Cash used in investing activities during the nine months ended September 30, 2017, was due primarily to net activity related to marketable securities of \$3.3 billion and capital expenditures of \$511 million. Capital expenditures during the nine months ended September 30, 2018 and 2017, were associated primarily with manufacturing-capacity expansions in various locations, as well as other site developments. We currently estimate 2018 spending on capital projects and equipment to be approximately \$700 million.

Financing

Cash used in financing activities during the nine months ended September 30, 2018, was due primarily to repurchases of our common stock of \$15.7 billion, payment of dividends of \$2.7 billion and repayment of debt of \$500 million. Cash used in financing activities during the nine months ended September 30, 2017, was due primarily to the payment of dividends of \$2.5 billion, repurchases of our common stock of \$2.4 billion and repayment of long-term debt, net of proceeds from debt issuances, of \$920 million, offset partially by net proceeds from the issuance of commercial paper of \$1.5 billion. See Note 12, Stockholders' equity, to the condensed consolidated financial statements for further discussion.

Critical accounting policies

The preparation of our condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, under different assumptions or conditions, actual results could differ materially from those estimates. A summary of our critical accounting policies is presented in Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2017. There were no material changes to our critical accounting policies during the nine months ended September 30, 2018.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Information about our market risk is disclosed in Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the year ended December 31, 2017, and is incorporated herein by reference. There have been no material changes during the nine months ended September 30, 2018, to the information provided in Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the year ended December 31, 2017.

Item 4. 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 September 30, 2018.

Management determined that, as of September 30, 2018, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

See Note 15, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Reports on Form 10-Q for the periods ended June 30, 2018 and September 30, 2018, and Note 14, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the period ended March 31, 2018, for discussions that are limited to certain recent developments concerning our legal proceedings. Those discussions should be read in conjunction with Note 18, Contingencies and commitments, to the consolidated financial statements in Part IV of our Annual Report on Form 10-K for the year ended December 31, 2017.

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. These statements are not guarantees of future performance, and involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. We have described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, the primary risks related to our business, and we periodically update those risks for material developments. Those risks are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Below, we are providing, in supplemental form, the material changes to our risk factors that occurred during the past quarter. Our risk factors disclosed in Part I, Item 1A, of our Annual Report, on Form 10-K for the year ended December 31, 2017, provide additional disclosure for these supplemental risks and are incorporated herein by reference.

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

Sales of our products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers continue to pursue initiatives to contain costs and manage drug utilization. These payers are increasingly focused on the effectiveness, benefits and costs of similar treatments, which could result for our products in lower reimbursement rates or narrower populations for whom payers will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payer dynamics, may limit our ability to set or adjust the price of our products based on their value, which could have a material adverse effect on our business. In the United States, the public discussions of drug pricing issues are likely to continue.

A substantial portion of our U.S. business relies on reimbursement from U.S. federal government healthcare programs and commercial insurance plans regulated by the U.S. federal and state governments. See our Annual Report on Form 10-K for the year ended December 31, 2017, Part I, Item 1. Business—Reimbursement. Changes to U.S. federal reimbursement policy may come through legislative and/or administrative actions. For example, in February 2018, the U.S. Congress passed legislation that requires biopharmaceutical manufacturers to pay greater discounts for patients in the Medicare Part D coverage gap beginning in 2019, which may reduce our net product sales relating to such patients. Other legislative proposals have been introduced into the U.S. Congress to overhaul provisions of the Patient Protection and Affordable Care Act (ACA) and to enable commercial-level re-importation of prescription medications from Canada or other countries. In May 2018, U.S. President Donald Trump and his administration released a drug pricing “blueprint” and requested public comment on an array of policy ideas intended to increase competition, improve the negotiating power of the federal government, reduce drug prices and lower patient out-of-pocket costs. The blueprint included a number of policy ideas with the potential to significantly impact, whether individually or collectively, our industry, including proposals to move coverage and reimbursement for Medicare Part B drugs into Medicare Part D, to require the inclusion of drug price information in direct-to-consumer drug advertising and to institute a competitive acquisition program for Part B drugs. The blueprint also proposed the removal of the safe-harbor protection under the federal anti-kickback statute for drug rebates paid to payers. Since the release of the

drug pricing blueprint, senior administration officials have continued to state publicly their strong interest in changing the U.S. drug reimbursement system to eliminate rebates. Rebates are payments by a biopharmaceutical manufacturer of a portion of product's purchase price back to the government program or private insurance plan responsible for paying for such product, or to the pharmacy benefit managers (PBMs) who administer the prescription drug programs for government and private employers. While significant uncertainty remains as to how these or other changes might be accomplished, removal of the existing federal anti-kickback statute safe harbor protection for rebates may call into question the legality of such rebates in federal healthcare programs. This development or other changes affecting the ability or willingness

of biopharmaceutical manufacturers to pay rebates could cause significant disruption in the current drug payment and reimbursement system. Changes in U.S. federal reimbursement policy may also arise as a result of executive actions, federal regulations, or demonstration projects implemented by federal agencies including 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 implement policy changes or demonstration projects that can quickly and significantly affect how our products are covered and reimbursed. CMS has already begun implementing certain elements described in the administration's drug pricing blueprint, including: issuing guidance to allow certain Medicare plans offered by private insurance companies to begin requiring that patients receiving Medicare Part B drugs first try a drug preferred by the plan before such plan will cover another therapy; and proposing new rules to require drug price information in direct-to-consumer (DTC) drug television advertising and to lower reimbursement rates for new Part B drugs launched beginning in 2019. Prior to CMS issuing its proposed DTC television advertising rule, we committed to the enhanced Pharmaceutical Research and Manufacturers of America voluntary DTC principles, which provide that, effective in 2019, all DTC television advertisements will direct patients to information about drug costs, including the list price of the medicine and out of pocket costs. On October 25, 2018, President Trump announced that CMS was evaluating a pilot program that proposes to set the Medicare payment amount for Part B single source drugs and biologics to more closely align with international drug prices and pay physicians and hospitals participating in such program a set drug add-on payment for administered drugs. CMS has since issued an advance notice of proposed rulemaking that requests public comment on the pilot program, which is proposed to initially cover fifty percent of Medicare Part B spending on separately payable Part B drugs. CMS has undertaken other projects to test care models, such as the CMS Oncology Care Model that provides participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare costs without negatively impacting the efficacy of care. We believe the Oncology Care Model has reduced utilization of certain of our oncology products by participating physician practices and may continue to do so in the future. In addition, CMS has solicited suggestions regarding other potential care models. Further, President Trump's administration is seeking to address drug prices through other federal agency actions. For example, to promote greater drug price competition, the FDA is pursuing policies that would ease generic and biosimilar entry requirements, including the lowering of standards for demonstrating biosimilarity or interchangeability. See We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future.

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

At the state level, government actions or ballot initiatives can also affect how our products are covered and reimbursed and/or create additional pressure on our pricing decisions. A number of states have adopted, and many other states have discussed and debated and are considering, new pricing legislation, including proposals designed to require biopharmaceutical manufacturers to publicly report proprietary pricing information, limit price increases or to place a maximum price ceiling or cap on biopharmaceutical products. For example, in October 2017, California enacted a drug pricing transparency bill that requires biopharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. In addition, the Ohio Department of Medicaid recently ordered that all of the state's Medicaid managed care plans terminate and renegotiate contracts with PBMs to eliminate the drug purchasing model in which PBMs bill the state more than they reimburse pharmacists for filling Medicaid patient prescriptions. Other states could adopt similar approaches, which could create additional uncertainty in the Medicaid reimbursement setting. These existing and proposed state pricing laws have added complexity to the pricing of drugs and may already be impacting industry pricing decisions. Ultimately, as with U.S. federal government actions, existing or future state government actions may also have a material adverse effect on our business and results of operations.

Payers, including healthcare insurers, PBMs and group purchasing organizations, increasingly seek ways to reduce their and their respective members' costs. Many payers continue to adopt benefit plan changes that shift a greater

portion of prescription costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient co-pay or co-insurance obligations and limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs). Payers have sought and will likely continue to seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage, particularly in treatment areas where the payer has taken the position that multiple branded products are therapeutically comparable. Payers also control costs by imposing restrictions on access to or usage of our products, such as requiring that the patient first try a drug preferred by the payer or receive the payer's prior authorization before covering the product, and may choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. For example, the burdensome administrative process required for physicians to demonstrate or document that the patients for whom Repatha® has been prescribed meet the payers' utilization management criteria has limited patient access to Repatha® treatment. In an effort to reduce access

burdens, we have taken a number of actions to reduce the net price of Repatha® through offering greater discounts and rebates to payers. Even with increased access, patient out-of-pocket expense has and may continue to limit patient use. For example, a very high percentage of Medicare patients have abandoned their Repatha® prescriptions rather than pay their co-pay payment. In October 2018, we introduced a set of new NDCs to make Repatha® available at a lower list price to attempt to address affordability for patients, particularly those on Medicare. Despite the recent net price reductions, payers may continue to restrict patient access, change formulary coverage for Repatha®, seek further discounts or rebates or take other actions that could reduce our sales of Repatha®. Further, our introduction of the new NDCs may not be rapidly adopted by payers, which could continue to limit patient use and could also reduce our sales of Repatha®.

Significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. For example, in the United States, the top three PBMs now oversee more than 70% of prescription claims and the top three health insurance companies' coverage is approaching half of government and commercial covered lives. Consolidation between pharmacies is also increasing, with the top three pharmacies now responsible for half of U.S. drug sales. The consolidation among insurers, PBMs and other payers, including through integrated delivery systems and/or with specialty pharmacies and pharmacy retailers, has increased the negotiating leverage such entities have over us and other drug manufacturers and has resulted in greater price discounts on our products, fees for other services and rebates. For example, U.S. regulators have recently approved the mergers of two of the nation's largest PBMs, Express Scripts and CVS Health, with major insurance companies Cigna and Aetna, respectively. Further consolidation would increase the leverage of such entities. Ultimately, additional discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products.

Outside the United States, we expect countries will continue to take actions to reduce their drug expenditures. See our Annual Report on Form 10-K for the year ended December 31, 2017, Part I, 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. In addition, countries may exclude or limit coverage and reimbursement for a product when their national health technology assessments do not indicate that the product demonstrates sufficient clinical benefit beyond existing therapies. For example, reimbursement for Repatha® in France and Germany may remain limited to relatively narrow patient populations following recent national health technology assessments. While the pricing and reimbursement process in those countries remains ongoing, these assessments have negatively impacted our efforts in France and Germany to expand Repatha® access to the broader patient population covered by the approved label. Any deterioration in the coverage and reimbursement available for our products or in the timeliness or certainty of payment by payers to physicians and other providers could negatively impact the ability or willingness of healthcare providers to prescribe our products for their patients or could otherwise negatively affect the use of our products or the prices we receive for them. Such changes could have a material adverse effect on our product sales, business and results of operations.

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

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

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

In the European Union, biosimilars are evaluated for marketing authorization pursuant to a set of general and product class-specific guidelines. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU countries have adopted and others are attempting to adopt biosimilar uptake measures such as requiring physician prescribing

quotas or promoting switching or pharmacy substitution of biosimilars for the corresponding reference products, and other countries may adopt similar measures. Some EU countries impose automatic price reductions upon market entry of one or more biosimilar competitors.

In the United States, the ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. See our Annual Report on Form 10-K for the year ended December 31, 2017, Part I, Item 1. Business—Government Regulation—Regulation in the United States—Approval of Biosimilars. The first biosimilar entrant into the U.S. market, Sandoz’s Zarxi®, is a biosimilar version of NEUPOGEN®, and was launched in the United States in 2015. Since then, the FDA has approved additional biosimilars, including biosimilar versions of ENBREL, Neulasta® and EPOGEN®, and a growing number of companies have announced that they are also developing biosimilar versions of our products. One biosimilar version of Neulasta® launched earlier this year and others may also receive approval in the near future; the approved biosimilar version of EPOGEN® may also launch. We believe that when multiple biosimilar versions of one of our products are approved and launched, competition could intensify more rapidly, resulting in a greater impact on such product’s sales. Companies pursuing development of biosimilar versions of our products have challenged and may continue to challenge our patents well in advance of the expiration of our material patents. For information related to our biosimilars and generics patent litigation, see Note 15, Contingencies and commitments, to the condensed consolidated financial statements, Note 18, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017, and Notes 14 and 15, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018, respectively. See also our Annual Report on Form 10-K for the year ended December 31, 2017, Part I, Item 1A. Risk Factors—Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in present and future intellectual property litigation. The U.S. pathway includes the option for biosimilar products that meet certain criteria to be approved as interchangeable with their reference products. Some companies currently developing or already marketing biosimilars may seek to register their products as interchangeable biosimilars, which could make it easier for pharmacists to substitute those biosimilars for our reference products or could encourage prescribers or payers who are inclined to select the interchangeable biosimilar over our innovative products or our biosimilars. In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law’s provisions regarding which new products receive data exclusivity. For example, the FDA is considering whether subsequent changes to a licensed biologic would be protected by the remainder of the reference product’s original 12-year exclusivity period (a concept known in the generic drug context as “umbrella exclusivity”). If the FDA were to decide that “umbrella exclusivity” does not apply to biological reference products or were to make other changes to the exclusivity period, this could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, public, legislative, and FDA efforts to promote price competition through policies enabling easier generic and biosimilar entry, including efforts to lower standards for demonstrating biosimilarity or interchangeability, and through changes to the reimbursement policies for biologics.

While most of our products are biologics, some of our products are small molecule products. Upon the expiration or loss of patent protection for a small molecule product, we can lose the majority of revenues for that product in a very short period of time. The FDA approval process exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy and allows generic manufacturers to rely on the safety and efficacy data of the innovator product, often enabling these generic competitors to market competing versions of our product after the expiration or loss of our patent at a much lower price. Our U.S. composition of matter patent for Sensipar®, a small molecule product, expired in March 2018. We are engaged in litigation with a number of companies seeking to market generic versions of Sensipar® surrounding our U.S. formulation patent that expires in September 2026. See Note 15, Contingencies and commitments, to the condensed consolidated financial statements, Note 18, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017, and Notes 14 and 15, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018 and June 30, 2018, respectively. Several of these generic versions of Sensipar® have been approved by the FDA, and one or more of these companies may elect to launch their approved generic versions at risk, prior to the conclusion of our ongoing

litigation. If this happens, our product sales for Sensipar® could be materially and adversely affected.

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

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

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. Professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities. Recommendations by government agencies or other groups and organizations may

relate to such matters as usage, dosage, route of administration and use of related therapies. In addition, a growing number of organizations are providing assessments of the value and pricing of biopharmaceutical products, and even organizations whose guidelines have historically been focused on clinical matters may begin to incorporate analyses of the cost effectiveness of various treatments into their treatment guidelines and recommendations. Value assessments may come from private organizations that publish their findings and offer recommendations relating to the products' reimbursement by government and private payers. Some companies and payers have announced pricing and payment decisions based in part on the assessments of private organizations. For example, CVS Caremark indicated in August 2018 that it will begin utilizing third-party cost effectiveness analyses to make formulary and coverage determinations for newly-approved drugs. In addition, government health technology assessment organizations in many countries make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service impact of new, emerging and existing medicines and treatments. Such health technology assessment organizations may recommend reimbursement for our product for a narrower indication than was approved by applicable regulatory agencies or may recommend against reimbursement entirely. Such recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could have a material adverse effect on our product sales, business and results of operations. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price of our common stock.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the three months ended September 30, 2018, we had one outstanding stock repurchase program, under which the repurchase activity was as follows:

Period	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⁾
July 1 - 31	3,018,400	\$191.69	3,018,400	\$4,814,509,041
August 1 - 31	3,197,500	\$197.03	3,197,500	\$4,184,499,911
September 1 - 30	2,498,600	\$202.12	2,498,600	\$3,679,470,791
Total	8,714,500	\$196.64	8,714,500	

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

⁽²⁾ In April 2018, our Board of Directors increased the amount authorized under our stock repurchase program by an additional \$5.0 billion.

Item 6. EXHIBITS

Reference is made to the Index to Exhibits included herein.

INDEX TO EXHIBITS

Exhibit No. Description

- 3.1 Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)

- 3.2 Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)

- 4.1 Form of stock certificate for the common stock, par value \$.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)

- 4.2 Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)

- 4.3 Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)

- 4.4 First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)

- 4.5 8-1/8% Debentures due April 1, 2007. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)

- 4.6 Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2007." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)

- 4.7 Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)

- 4.8 Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)

- 4.9 Officers' Certificate of Amgen Inc., dated May 30, 2007, including forms of the Company's Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)

- 4.10 Officers' Certificate of Amgen Inc., dated May 23, 2008, including forms of the Company's 6.15% Senior Notes due 2018 and 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)

- 4.11 Officers' Certificate of Amgen Inc., dated January 16, 2009, including forms of the Company's 5.70% Senior Notes due 2019 and 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)

- 4.12 Officers' Certificate of Amgen Inc., dated March 12, 2010, including forms of the Company's 4.50% Senior Notes due 2020 and 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.)

- 4.13 Officers' Certificate of Amgen Inc., dated September 16, 2010, including forms of the Company's 3.45% Senior Notes due 2020 and 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)
- 4.14 Officers' Certificate of Amgen Inc., dated June 30, 2011, including forms of the Company's 2.30% Senior Notes due 2016, 4.10% Senior Notes due 2021 and 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)
- 4.15 Officers' Certificate of Amgen Inc., dated November 10, 2011, including forms of the Company's 1.875% Senior Notes due 2014, 2.50% Senior Notes due 2016, 3.875% Senior Notes due 2021 and 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)
- 4.16 Officers' Certificate of Amgen Inc., dated December 5, 2011, including forms of the Company's 4.375% Senior Notes due 2018 and 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)

Exhibit No.	Description
4.17	<u>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.</u> (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)
4.18	<u>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.</u> (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)
4.19	<u>Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee.</u> (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
4.20	<u>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.</u> (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
4.21	<u>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.</u> (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.)
4.22	<u>Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including forms of the Company's 1.250% Senior Notes due 2022 and 2.000% Senior Notes due 2026.</u> (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.)
4.23	<u>Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023.</u> (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.24	<u>Terms of the Bonds for the Company's 0.410% bonds due 2023.</u> (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.25	<u>Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051.</u> (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.26	<u>Registration Rights Agreement, dated as of June 14, 2016, by and among Amgen Inc., Credit Suisse Securities (USA) LLC, J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Mizuho Securities USA Inc., as lead dealer managers, and Drexel Hamilton, LLC and The Williams Capital Group, L.P., as co-dealer managers.</u> (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.27	<u>Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 1.850% Senior Notes due 2021, 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026.</u> (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.28	<u>Officer's Certificate of Amgen Inc., dated as of May 11, 2017, including forms of the Company's Senior Floating Rate Notes due 2019, Senior Floating Rate Notes due 2020, 1.900% Senior Notes due 2019, 2.200% Senior Notes due 2020 and 2.650% Senior Notes due 2022.</u> (Filed as an exhibit to Form 8-K on May 11, 2017 and incorporated herein by reference.)

- 4.29 Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated by reference.)
- 10.1+ Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
- 10.2+ First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.)
- 10.3+ Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)
- 10.4+ Form of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 12, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)

Edgar Filing: AMGEN INC - Form 10-Q

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

Edgar Filing: AMGEN INC - Form 10-Q

Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)

10.18+ Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)

10.19+ First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)

10.20+ Agreement between Amgen Inc. and David W. Meline, effective July 21, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2014 on October 29, 2014 and incorporated herein by reference.)

10.21+ Agreement between Amgen Inc. and Jonathan Graham, dated May 11, 2015. (Filed as an exhibit to Form 10-Q/A for the quarter ended June 30, 2015 on August 6, 2015 and incorporated herein by reference.)

10.22+ Agreement between Amgen Inc. and Lori Johnston, dated October 25, 2016. (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)

10.23+* Agreement between Amgen Inc. and Murdo Gordon, dated July 25, 2018.

Edgar Filing: AMGEN INC - Form 10-Q

Exhibit No.	Description
10.24	<u>Amended and Restated Credit Agreement, dated July 30, 2014, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent (the "Credit Agreement").</u> (Filed as an exhibit to Form 8-K on July 30, 2014 and incorporated herein by reference.)
10.25	<u>Amendment No. 1 to the Credit Agreement, dated March 9, 2018, among Amgen Inc., the Banks therein named, and Citibank, N.A., as administrative agent.</u> (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.)
10.26	<u>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).</u> (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)
10.27	<u>Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment).</u> (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.28	<u>Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc.</u> (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)
10.29	<u>Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc.</u> (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.30	<u>Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc.</u> (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.31	<u>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.</u> (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.32	<u>Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc.</u> (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.33	<u>Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc.</u> (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
10.34	<u>Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc.</u> (portions of the exhibit have been omitted pursuant to a

request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)

10.35 Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

10.36 Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

10.37 Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

10.38 Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

Exhibit No. Description

- 10.39 Amendment No. 1 to the Collaboration Agreement, dated March 20, 2018, by and between Novartis Pharma AG and Amgen Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.)
- 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 Quarterly Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Amgen Inc.
(Registrant)

Date: October 30, 2018 By: /S/ DAVID W. MELINE

David W. Meline
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)