

AMGEN INC

Form 10-Q

October 26, 2017

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, 2017

OR

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

Commission file number 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware

(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer Non-accelerated filer
(Do not check if a smaller reporting company)

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 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 17, 2017, the registrant had 725,910,575 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>27</u>
Item 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>37</u>
Item 4. <u>CONTROLS AND PROCEDURES</u>	<u>38</u>
<u>PART II - OTHER INFORMATION</u>	<u>38</u>
Item 1. <u>LEGAL PROCEEDINGS</u>	<u>38</u>
Item 1A. <u>RISK FACTORS</u>	<u>38</u>
Item 2. <u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	<u>40</u>
Item 6. <u>EXHIBITS</u>	<u>40</u>
<u>SIGNATURES</u>	<u>41</u>
<u>INDEX TO EXHIBITS</u>	<u>42</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, 2017		Nine months ended September 30, 2016	
Revenues:				
Product sales	\$5,453	\$5,516	\$16,226	\$16,229
Other revenues	320	295	821	797
Total revenues	5,773	5,811	17,047	17,026
Operating expenses:				
Cost of sales	990	1,027	3,010	3,095
Research and development	877	990	2,519	2,762
Selling, general and administrative	1,170	1,244	3,443	3,739
Other	297	23	347	121
Total operating expenses	3,334	3,284	9,319	9,717
Operating income	2,439	2,527	7,728	7,309
Interest expense, net	325	325	972	932
Interest and other income, net	267	216	627	503
Income before income taxes	2,381	2,418	7,383	6,880
Provision for income taxes	360	401	1,140	1,093
Net income	\$2,021	\$2,017	\$6,243	\$5,787
Earnings per share:				
Basic	\$2.78	\$2.70	\$8.52	\$7.70
Diluted	\$2.76	\$2.68	\$8.46	\$7.63
Shares used in calculation of earnings per share:				
Basic	728	747	733	752
Diluted	733	753	738	758
Dividends paid per share	\$1.15	\$1.00	\$3.45	\$3.00

See accompanying notes.

AMGEN INC.
 CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
 (In millions)
 (Unaudited)

	Three months ended September 30, 2017		Nine months ended September 30, 2016	
Net income	\$2,021	\$2,017	\$6,243	\$5,787
Other comprehensive income (loss), net of reclassification adjustments and taxes:				
Foreign currency translation gains	41	9	100	25
Effective portion of cash flow hedges	(50)	(16)	(324)	(201)
Net unrealized gains (losses) on available-for-sale securities	9	(27)	247	515
Other	6	1	5	2
Other comprehensive income (loss), net of taxes	6	(33)	28	341
Comprehensive income	\$2,027	\$1,984	\$6,271	\$6,128

See accompanying notes.

AMGEN INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(In millions, except per share data)

	September 30, 2017	December 31, 2016
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,000	\$ 3,241
Marketable securities	38,351	34,844
Trade receivables, net	3,404	3,165
Inventories	2,927	2,745
Other current assets	2,070	2,015
Total current assets	49,752	46,010
Property, plant and equipment, net	4,914	4,961
Intangible assets, net	8,873	10,279
Goodwill	14,776	14,751
Other noncurrent assets	2,016	1,625
Total assets	\$ 80,331	\$ 77,626
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 879	\$ 917
Accrued liabilities	5,315	5,884
Short-term borrowings and current portion of long-term debt	1,999	4,403
Total current liabilities	8,193	11,204
Long-term debt	33,777	30,193
Long-term deferred tax liabilities	2,131	2,436
Long-term tax liabilities	2,733	2,419
Other noncurrent liabilities	1,268	1,499
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; \$0.0001 par value; 2,750.0 shares authorized; outstanding — 726.6 shares in 2017 and 738.2 shares in 2016	30,898	30,784
Retained earnings (accumulated deficit)	1,774	(438)
Accumulated other comprehensive loss	(443)	(471)
Total stockholders' equity	32,229	29,875
Total liabilities and stockholders' equity	\$ 80,331	\$ 77,626

See accompanying notes.

AMGEN INC.
 CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
 (In millions)
 (Unaudited)

	Nine months ended September 30, 2017 2016	
Cash flows from operating activities:		
Net income	\$6,243	\$5,787
Depreciation and amortization	1,506	1,546
Share-based compensation expense	244	222
Deferred income taxes	(379)	80
Other items, net	381	93
Changes in operating assets and liabilities:		
Trade receivables, net	(229)	(192)
Inventories	(54)	(125)
Other assets	(110)	(335)
Accounts payable	(50)	(147)
Accrued income taxes, net	48	(140)
Other liabilities	565	465
Net cash provided by operating activities	8,165	7,254
Cash flows from investing activities:		
Purchases of property, plant and equipment	(511)	(511)
Purchases of marketable securities	(26,661)	(22,682)
Proceeds from sales of marketable securities	18,580	14,072
Proceeds from maturities of marketable securities	4,765	1,932
Other	(119)	(247)
Net cash used in investing activities	(3,946)	(7,436)
Cash flows from financing activities:		
Net proceeds from issuance of debt	3,485	6,713
Repayment of debt	(4,405)	(2,725)
Net change in commercial paper	1,499	—
Repurchases of common stock	(2,371)	(1,982)
Dividends paid	(2,531)	(2,251)
Other	(137)	(232)
Net cash used in financing activities	(4,460)	(477)
Decrease in cash and cash equivalents	(241)	(659)
Cash and cash equivalents at beginning of period	3,241	4,144
Cash and cash equivalents at end of period	\$3,000	\$3,485

See accompanying notes.

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2017

(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, 2017 and 2016, 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, 2016, 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, 2017 and June 30, 2017.

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 \$7.5 billion as of September 30, 2017 and December 31, 2016.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB has 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 are effective for interim and annual periods beginning on January 1, 2018. The new standards are required to be adopted using either a full-retrospective or a modified-retrospective approach. We expect to adopt this standard by using the modified-retrospective approach beginning in 2018. We have completed our impact assessment and do not currently anticipate a material impact on Total revenues in our Consolidated Statements of Income. We are implementing changes to our accounting policies, business processes, internal controls and disclosures to support the new accounting, however these changes are not expected to be significant.

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. The new standard is effective for interim and annual periods beginning on January 1, 2018. With the exception of equity investments currently being accounted for at cost, adjustments are applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. The new standard will be applied prospectively to investments currently accounted for at cost. The impact that this new standard will have on our consolidated financial statements will depend on the fair value of available-for-sale equity securities in our portfolio in the future. See Note 6, Available-for-sale investments, for the

fair value of equity securities as of September 30, 2017.

5

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 the assets and liabilities that arise from leases on the balance sheet, 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. We expect to adopt this standard beginning in 2019. We do not expect that this standard will have a material impact on our Consolidated Statements of Income, but we do expect that upon adoption, this standard will have a material impact on our assets and liabilities on our Consolidated Balance Sheets. The primary effect of adoption will be the requirement to record right-of-use assets and corresponding lease obligations for current operating leases. In addition, the standard will require that we update our systems, processes and controls we use to track, record and account for our lease portfolio.

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 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 consolidated financial statements.

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. The new standard is effective for interim and annual periods beginning on January 1, 2018, but may be adopted earlier. We expect to adopt this standard beginning in 2018. The standard would be applied prospectively to any transaction occurring on or after the adoption date. We have completed our impact assessment and do not currently anticipate a material impact on our consolidated financial statements.

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 narrows the definition of outputs. The new standard will be applied prospectively and is effective for interim and annual periods beginning on January 1, 2018, but may be adopted earlier. We expect to adopt this standard beginning in 2018. Adoption of this new standard may result in more transactions being accounted for as asset acquisitions versus business combinations; however, the impact on our consolidated financial statements will depend on the facts and circumstances of future transactions.

2. Restructuring

In 2014, we initiated a restructuring plan to invest in both 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 continue to estimate that we will incur \$800 million to \$900 million of pre-tax charges in connection with our restructuring, including (i) separation and other headcount-related costs of \$535 million to \$585 million with respect to staff reductions and (ii) asset-related charges of \$265 million to \$315 million that consist primarily of asset impairments, accelerated depreciation and other related costs resulting from the consolidation of our worldwide facilities. Through September 30, 2017, we incurred a total of \$532 million of separation and other headcount-related costs and \$239 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, 2017 and 2016, were not significant. As of September 30, 2017, the total restructuring liability was not significant.

3. Income taxes

The effective tax rates for the three and nine months ended September 30, 2017, were 15.1% and 15.4%, respectively, compared with 16.6% and 15.9%, respectively, for the corresponding periods of the prior year. The effective rates differ from the federal statutory rates primarily as a result of indefinitely invested earnings of our foreign operations. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be invested indefinitely outside the United States.

The decrease in our effective tax rate for the three months ended September 30, 2017, was due primarily to favorable tax impacts of changes in the jurisdictional mix of income and expenses, as well as discrete benefits associated with the impairment of our AMG 899 (formerly TA-8995) asset and the related release of contingent consideration liabilities connected with the acquisition of Dezima Pharma B.V. (Dezima) (see Note 8, Goodwill and other intangible assets and Note 11, Fair value measurement), offset partially by adjustments to certain federal tax credits and deductions.

The decrease in our effective tax rate for the nine months ended September 30, 2017, was due primarily to favorable tax impacts of changes in the jurisdictional mix of income and expenses, as well as discrete benefits associated with the effective settlement of certain state and federal tax matters, offset partially by lower tax benefits from share-based compensation payments and adjustments to certain federal tax credits and deductions.

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 is 4% and 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. We are in discussions with the IRS examination team and understand that the RAR may be modified. 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. In addition, we are currently under examination by a number of other state and foreign tax jurisdictions.

During the three and nine months ended September 30, 2017, the gross amounts of our unrecognized tax benefits (UTBs) increased approximately \$120 million and \$345 million, respectively, as a result of tax positions taken during the current year. Substantially all of the UTBs as of September 30, 2017, if recognized, would affect our effective tax rate.

4. 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 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, 2017		Nine months ended September 30, 2016	
Income (Numerator):				
Net income for basic and diluted EPS	\$2,021	\$2,017	\$6,243	\$5,787

Shares (Denominator):

Weighted-average shares for basic EPS	728	747	733	752
Effect of dilutive securities	5	6	5	6
Weighted-average shares for diluted EPS	733	753	738	758

Basic EPS	\$2.78	\$2.70	\$8.52	\$7.70
Diluted EPS	\$2.76	\$2.68	\$8.46	\$7.63

For the three and nine months ended September 30, 2017 and 2016, the number of anti-dilutive employee share-based awards excluded from the computation of diluted EPS was not significant.

5. 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 research and development (R&D), manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for non-refundable up-front license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaborative arrangements are performed with no guarantee of either technological or commercial success, and each is unique in nature. 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, 2016. Novartis Pharma AG

In April 2017, we expanded our existing migraine collaboration with Novartis Pharma AG (Novartis), a wholly owned subsidiary of Novartis AG. In the United States, Amgen and Novartis will jointly develop and collaborate on the commercialization of AimovigTM (erenumab). Amgen, as the principal, will recognize product sales of AimovigTM in the United States, will share U.S. commercialization costs with Novartis and will pay Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan. Novartis will pay Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories. Novartis will fund a portion of global R&D expenses. Novartis will also make payments to Amgen that could collectively exceed \$400 million if certain regulatory events occur and commercial thresholds are achieved. Amgen will manufacture and supply AimovigTM worldwide.

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

During the three months ended September 30, 2017 and 2016, costs recovered from Novartis for the migraine products were \$29 million and \$6 million, respectively. During the nine months ended September 30, 2017 and 2016, costs recovered from Novartis for the migraine products were \$86 million and \$26 million, respectively. Costs recovered are included primarily in Research and development expense in the Condensed Consolidated Statements of Income. During the three months ended September 30, 2017, we received a milestone payment of \$60 million from

Novartis, which was recorded in Other revenues in the Condensed Consolidated Statements of Income.

8

6. 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):

Type of security as of September 30, 2017	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
U.S. Treasury securities	\$ 8,029	\$ 6	\$ (17)	\$8,018
Other government-related debt securities:				
U.S.	225	—	(1)	224
Foreign and other	2,634	41	(4)	2,671
Corporate debt securities:				
Financial	10,198	63	(7)	10,254
Industrial	9,829	94	(17)	9,906
Other	1,251	12	(2)	1,261
Residential mortgage-backed securities	2,212	2	(10)	2,204
Other mortgage- and asset-backed securities	2,071	—	(4)	2,067
Money market mutual funds	2,455	—	—	2,455
Other short-term interest-bearing securities	1,746	—	—	1,746
Total interest-bearing securities	40,650	218	(62)	40,806
Equity securities	129	27	(13)	143
Total available-for-sale investments	\$ 40,779	\$ 245	\$ (75)	\$40,949
Type of security as of December 31, 2016	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
U.S. Treasury securities	\$ 6,681	\$ 1	\$ (68)	\$6,614
Other government-related debt securities:				
U.S.	302	—	(3)	299
Foreign and other	1,784	9	(34)	1,759
Corporate debt securities:				
Financial	8,476	21	(37)	8,460
Industrial	8,793	59	(63)	8,789
Other	1,079	5	(7)	1,077
Residential mortgage-backed securities	1,968	1	(29)	1,940
Other mortgage- and asset-backed securities	1,731	1	(13)	1,719
Money market mutual funds	2,782	—	—	2,782
Other short-term interest-bearing securities	4,188	—	—	4,188
Total interest-bearing securities	37,784	97	(254)	37,627
Equity securities	127	31	(4)	154
Total available-for-sale investments	\$ 37,911	\$ 128	\$ (258)	\$37,781

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

Classification in the Condensed Consolidated Balance Sheets	September 30, December 31,	
	2017	2016
Cash and cash equivalents	\$ 2,455	\$ 2,783
Marketable securities	38,351	34,844
Other noncurrent assets	143	154
Total available-for-sale investments	\$ 40,949	\$ 37,781

Cash and cash equivalents in the above table excludes bank account cash of \$545 million and \$458 million as of September 30, 2017 and December 31, 2016, respectively.

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

Contractual maturity	September 30, December 31,	
	2017	2016
Maturing in one year or less	\$ 6,478	\$ 8,393
Maturing after one year through three years	12,912	10,404
Maturing after three years through five years	13,830	12,157
Maturing after five years through ten years	3,252	2,974
Maturing after ten years	63	40
Mortgage- and asset-backed securities	4,271	3,659
Total interest-bearing securities	\$ 40,806	\$ 37,627

For the three months ended September 30, 2017 and 2016, realized gains totaled \$38 million and \$215 million, respectively, and realized losses totaled \$12 million and \$192 million, respectively. For the nine months ended September 30, 2017 and 2016, realized gains totaled \$113 million and \$283 million, respectively, and realized losses totaled \$183 million and \$313 million, respectively. The cost of securities sold is based on the specific identification method.

Information on 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 was as follows (in millions):

Type of security as of September 30, 2017	Less than 12 months		12 months or more	
	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	\$6,242	\$ (17)	\$5	\$ —
Other government-related debt securities:				
U.S.	118	(1)	12	—
Foreign and other	515	(2)	65	(2)
Corporate debt securities:				
Financial	1,997	(6)	151	(1)
Industrial	2,434	(14)	276	(3)
Other	326	(2)	26	—
Residential mortgage-backed securities	1,723	(8)	94	(2)
Other mortgage- and asset-backed securities	1,074	(4)	38	—
Equity securities	13	(13)	—	—
Total	\$14,442	\$ (67)	\$667	\$ (8)

Edgar Filing: AMGEN INC - Form 10-Q

Type of security as of December 31, 2016	Less than 12 months		12 months or more	
	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	\$5,774	\$ (68)	\$—	\$ —
Other government-related debt securities:				
U.S.	201	(3)	—	—
Foreign and other	1,192	(34)	17	—
Corporate debt securities:				
Financial	3,975	(37)	44	—
Industrial	3,913	(61)	149	(2)
Other	486	(7)	7	—
Residential mortgage-backed securities	1,631	(26)	158	(3)
Other mortgage- and asset-backed securities	1,087	(10)	118	(3)
Equity securities	22	(4)	—	—
Total	\$18,281	\$ (250)	\$493	\$ (8)

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, 2017 and December 31, 2016, we believe the cost bases for our available-for-sale investments were recoverable in all material respects.

7. Inventories

Inventories consisted of the following (in millions):

	September 30, 2017	December 31, 2016
Raw materials	\$ 318	\$ 225
Work in process	1,597	1,608
Finished goods	1,012	912
Total inventories	\$ 2,927	\$ 2,745

8. Goodwill and other intangible assets

Goodwill

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

	Nine months ended September 30,	
	2017	2016
Beginning balance	\$14,751	\$14,787
Goodwill related to acquisitions of businesses	—	2
Currency translation adjustments	25	13
Ending balance	\$14,776	\$14,802

Identifiable intangible assets

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

	September 30, 2017			December 31, 2016		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
Finite-lived intangible assets:						
Developed product technology rights	\$ 12,585	\$ (6,624)	\$ 5,961	\$ 12,534	\$ (5,947)	\$ 6,587
Licensing rights	3,275	(1,525)	1,750	3,275	(1,300)	1,975
Marketing-related rights	1,326	(895)	431	1,333	(793)	540
Research and development technology rights	1,158	(783)	375	1,122	(704)	418
Total finite-lived intangible assets	18,344	(9,827)	8,517	18,264	(8,744)	9,520
Indefinite-lived intangible assets:						
In-process research and development	356	—	356	759	—	759
Total identifiable intangible assets	\$ 18,700	\$ (9,827)	\$ 8,873	\$ 19,023	\$ (8,744)	\$ 10,279

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 milestones, royalties and profit sharing payments, capitalized payments to third parties for milestones related to regulatory approvals to commercialize products and up-front payments associated with royalty obligations for marketed products. Marketing-related 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, 2017, we decided to discontinue the internal development of AMG 899 acquired in the acquisition of Dezima in 2015, resulting in an impairment charge of \$400 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 Statement of Cash Flows. See Note 11, Fair value measurement, for the impact on the related contingent consideration liabilities. As of September 30, 2017, the primary IPR&D project is oprozomib, acquired in the acquisition of Onyx Pharmaceuticals, Inc. in 2013.

All IPR&D projects have major risks and uncertainties associated with the timely and successful completion of 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, impact the revenues a product can generate. Consequently, the eventual realized value, if any, of the acquired IPR&D projects may vary from their estimated fair values. We review IPR&D projects for impairment annually, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon the establishment of technological feasibility or regulatory approval.

During the three months ended September 30, 2017 and 2016, we recognized amortization charges associated with our finite-lived intangible assets of \$308 million and \$371 million, respectively. During both the nine months ended September 30, 2017 and 2016, we recognized amortization charges associated with our finite-lived intangible assets of \$1.1 billion. The total estimated amortization charges for our finite-lived intangible assets for the remaining three months ending December 31, 2017, and the years ending December 31, 2018, 2019, 2020, 2021 and 2022, are \$0.3 billion, \$1.2 billion, \$1.1 billion, \$1.1 billion, \$0.9 billion and \$0.9 billion, respectively.

9. Financing arrangements

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

	September 30, 2017	December 31, 2016
Commercial paper	\$ 1,500	\$ —
Short-term loan	—	605
2.125% notes due 2017 (2.125% 2017 Notes)	—	1,250
Floating Rate Notes due 2017	—	600
1.25% notes due 2017 (1.25% 2017 Notes)	—	850
5.85% notes due 2017 (5.85% 2017 Notes)	—	1,100
6.15% notes due 2018 (6.15% 2018 Notes)	500	500
4.375% €550 million notes due 2018 (4.375% 2018 euro Notes)	647	577
5.70% notes due 2019 (5.70% 2019 Notes)	1,000	1,000
1.90% notes due 2019 (1.90% 2019 Notes)	700	—
Floating Rate Notes due 2019	550	250
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)	797	710
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	—
2.20% notes due 2020 (2.20% 2020 Notes)	700	—

Edgar Filing: AMGEN INC - Form 10-Q

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)	1,478	1,315
2.70% notes due 2022 (2.70% 2022 Notes)	500	500
2.65% notes due 2022 (2.65% 2022 Notes)	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)	723	687
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)	886	789
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)	636	586
	938	864

4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)			
6.375% notes due 2037 (6.375% 2037 Notes)	552		552
6.90% notes due 2038 (6.90% 2038 Notes)	291		291
6.40% notes due 2039 (6.40% 2039 Notes)	466		466
5.75% notes due 2040 (5.75% 2040 Notes)	412		412
4.95% notes due 2041 (4.95% 2041 Notes)	600		600
5.15% notes due 2041 (5.15% 2041 Notes)	974		974
5.65% notes due 2042 (5.65% 2042 Notes)	487		487
5.375% notes due 2043 (5.375% 2043 Notes)	261		261
4.40% notes due 2045 (4.40% 2045 Notes)	2,250		2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415		1,415
4.663% notes due 2051 (4.663% 2051 Notes)	3,541		3,541
Other notes due 2097	100		100
Unamortized bond discounts, premiums and issuance costs, net	(928))	(936)
Total carrying value of debt	35,776		34,596
Less current portion	(1,999))	(4,403)
Total noncurrent debt	\$ 33,777		\$ 30,193

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 approximately 6.3% and 5.6%, respectively.

Debt repayments

During the nine months ended September 30, 2017, we repaid the \$605 million short-term loan, the \$1.25 billion aggregate principal amount of the 2.125% 2017 Notes, the \$600 million aggregate principal amount of the Floating Rate Notes due 2017, the \$850 million aggregate principal amount of the 1.25% 2017 Notes and the \$1.1 billion aggregate principal amount of the 5.85% 2017 Notes.

Debt issuances

In May 2017, we issued a \$3.5 billion principal amount of notes, consisting of the Floating Rate Notes due 2019, the 1.90% 2019 Notes, the Floating Rate Notes due 2020, the 2.20% 2020 Notes and the 2.65% 2022 Notes. In the event of a change-of-control triggering event, as defined in the terms of the notes, we may be required to purchase all or a portion of these debt securities at a price equal to 101% of the principal amount of the notes plus accrued and unpaid interest. All of the aforementioned fixed-rate notes may be redeemed at any time, in whole or in part, at the principal amount of the notes being redeemed plus accrued and unpaid interest and, except for the 2.65% 2022 Notes, a make-whole amount, which is defined by the terms of the notes. The 2.65% 2022 Notes may be redeemed without payment of the make-whole amount if redemption occurs on or after one month prior to maturity.

During the nine months ended September 30, 2017, we issued commercial paper under our commercial paper program. As of September 30, 2017, the weighted-average effective borrowing rate on outstanding commercial paper was 1.3%.

10. Stockholders' equity

Stock repurchase program

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

	2017		2016	
	Share	Dollars	Share	Dollars
First quarter	3.4	\$ 555	4.7	\$ 690
Second quarter	6.2	1,006	3.9	591
Third quarter	4.4	769	4.4	747
Total stock repurchases	14.0	\$ 2,330	12.9	\$ 2,028

* Shares do not foot due to rounding.

As of September 30, 2017, \$1.7 billion remained available under our stock repurchase program. In October 2017, our Board of Directors authorized an increase that resulted in a total of \$5.0 billion available under the stock repurchase program.

Dividends

In July 2017, March 2017 and December 2016, the Board of Directors declared quarterly cash dividends of \$1.15 per share of common stock, which were paid in September 2017, June 2017 and March 2017, respectively. In October 2017, the Board of Directors declared a quarterly cash dividend of \$1.15 per share of common stock, which will be paid on December 8, 2017.

Accumulated other comprehensive income (loss)

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

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2016	\$ (610)	\$ 282	\$ (138)	\$ (5)	\$(471)
Foreign currency translation adjustments	21	—	—	—	21
Unrealized gains	—	17	116	—	133
Reclassification adjustments to income	—	(131)	49	—	(82)
Income taxes	3	41	(7)	—	37
Balance as of March 31, 2017	(586)	209	20	(5)	(362)
Foreign currency translation adjustments	37	—	—	—	37
Unrealized gains	—	17	73	—	90
Reclassification adjustments to income	—	(330)	47	—	(283)
Other	—	—	—	(1)	(1)
Income taxes	(2)	112	(40)	—	70
Balance as of June 30, 2017	(551)	8	100	(6)	(449)
Foreign currency translation adjustments	38	—	—	—	38
Unrealized gains	—	65	41	—	106
Reclassification adjustments to income	—	(140)	(26)	—	(166)
Other	—	—	—	6	6
Income taxes	3	25	(6)	—	22
Balance as of September 30, 2017	\$ (510)	\$ (42)	\$ 109	\$—	\$(443)

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

Components of AOCI	Amounts reclassified out of AOCI	Three months ended September 30,	Line item affected in the Condensed Consolidated Statements of Income
	2017	2016	
Cash flow hedges:			
Foreign currency contract (losses) gains	\$ (2)	\$ 67	Product sales
Cross-currency swap contract gains (losses)	143	(1)	Interest and other income, net
Forward interest rate contract losses	(1)	(1)	Interest expense, net
	140	65	Income before income taxes
	(49)	(27)	Provision for income taxes
	\$ 91	\$ 38	Net income
Available-for-sale securities:			
Net realized gains	\$ 26	\$ 23	Interest and other income, net
	(5)	(8)	Provision for income taxes
	\$ 21	\$ 15	Net income

Components of AOCI	Amounts reclassified out of AOCI Nine months ended September 30,		Line item affected in the Condensed Consolidated Statements of Income
	2017	2016	
Cash flow hedges:			
Foreign currency contract gains	\$88	\$242	Product sales
Cross-currency swap contract gains (losses)	514	(143)	Interest and other income, net
Forward interest rate contract losses	(1)	(1)	Interest expense, net
	601	98	Income before income taxes
	(213)	(39)	Provision for income taxes
	\$388	\$59	Net income
Available-for-sale securities:			
Net realized losses	\$(70)	\$(30)	Interest and other income, net
	(7)	—	Provision for income taxes
	\$(77)	\$(30)	Net income

11. 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.

Edgar Filing: AMGEN INC - Form 10-Q

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, 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:				
Available-for-sale investments:				
U.S. Treasury securities	\$ 8,018	\$ —	\$ —	\$8,018
Other government-related debt securities:				
U.S.	—	224	—	224
Foreign and other	—	2,671	—	2,671
Corporate debt securities:				
Financial	—	10,254	—	10,254
Industrial	—	9,906	—	9,906
Other	—	1,261	—	1,261
Residential mortgage-backed securities	—	2,204	—	2,204
Other mortgage- and asset-backed securities	—	2,067	—	2,067
Money market mutual funds	2,455	—	—	2,455
Other short-term interest-bearing securities	—	1,746	—	1,746
Equity securities	143	—	—	143
Derivatives:				
Foreign currency contracts	—	7	—	7
Cross-currency swap contracts	—	224	—	224
Interest rate swap contracts	—	40	—	40
Forward interest rate contracts	—	10	—	10
Total assets	\$ 10,616	\$ 30,614	\$ —	\$41,230
Liabilities:				
Derivatives:				
Foreign currency contracts	\$ —	\$ 179	\$ —	\$179
Cross-currency swap contracts	—	308	—	308
Interest rate swap contracts	—	5	—	5
Contingent consideration obligations in connection with business combinations	—	—	68	68
Total liabilities	\$ —	\$ 492	\$ 68	\$560

Edgar Filing: AMGEN INC - Form 10-Q

Fair value measurement as of December 31, 2016, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale investments:				
U.S. Treasury securities	\$ 6,614	\$ —	\$ —	\$6,614
Other government-related debt securities:				
U.S.	—	299	—	299
Foreign and other	—	1,759	—	1,759
Corporate debt securities:				
Financial	—	8,460	—	8,460
Industrial	—	8,789	—	8,789
Other	—	1,077	—	1,077
Residential mortgage-backed securities	—	1,940	—	1,940
Other mortgage- and asset-backed securities	—	1,719	—	1,719
Money market mutual funds	2,782	—	—	2,782
Other short-term interest-bearing securities	—	4,188	—	4,188
Equity securities	154	—	—	154
Derivatives:				
Foreign currency contracts	—	203	—	203
Interest rate swap contracts	—	41	—	41
Total assets	\$ 9,550	\$ 28,475	\$ —	\$38,025
Liabilities:				
Derivatives:				
Foreign currency contracts	\$ —	\$ 4	\$ —	\$4
Cross-currency swap contracts	—	523	—	523
Interest rate swap contracts	—	7	—	7
Contingent consideration obligations in connection with business combinations	—	—	179	179
Total liabilities	\$ —	\$ 534	\$ 179	\$713

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 Moody's Investors Service, Inc. (Moody's), and BBB+ or equivalent by Standard & Poor's Financial Services LLC (S&P) 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 utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. 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 utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. The inputs include reported trades of and broker/dealer

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

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

All of our foreign currency forward and option derivatives contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A- or equivalent by S&P or Moody's. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable, either directly or indirectly. The inputs include foreign currency exchange rates, London Interbank Offered Rates (LIBOR), swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. The inputs, when applicable, are at commonly quoted intervals. See Note 12, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A- or equivalent by S&P or Moody's. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable either directly or indirectly. The inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. See Note 12, Derivative instruments. Our interest rate swap contracts are with counterparties that have minimum credit ratings of A- or equivalent by S&P or Moody's. 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. The inputs included LIBOR, swap rates and obligor credit default swap rates.

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 estimated fair values by using probability-adjusted discounted cash flows, and we revalue the 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 product candidates acquired in business combinations and are reviewed quarterly by management in our R&D and commercial sales organizations. The 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, 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,		Nine months ended September 30,	
	2017	2016	2017	2016
Beginning balance	\$182	\$171	\$179	\$188
Net changes in valuation	(114)	5	(111)	(12)
Ending balance	\$68	\$176	\$68	\$176

As a result of our acquisition of Dezima in October 2015, we are obligated to pay its former shareholders up to \$1.25 billion of additional consideration contingent upon achieving certain development and sales-related milestones and low single-digit royalties on net product sales above a certain threshold for AMG 899. The estimated fair value of the contingent consideration obligations had an aggregate value of \$110 million at acquisition. During the three months ended September 30, 2017, we decided to discontinue the internal development of AMG 899, resulting in the release of the contingent consideration liabilities. The remeasurement of these liabilities of \$116 million was recognized in Other operating expenses in the Condensed Consolidated Statements of Income and included in Other items, net in the Condensed Consolidated Statement of Cash Flows. See Note 8, Goodwill and other intangible assets, for the impact on the related IPR&D asset.

As a result of our acquisition of BioVex Group, Inc. in 2011, we are obligated to pay its former shareholders up to \$325 million of additional consideration contingent upon the achievement of certain sales thresholds related to IMLYGIC® (talimogene laherparepvec) within specified periods of time.

During the nine months ended September 30, 2017 and 2016, there were no transfers of assets or liabilities between fair value measurement levels, and, except with respect to an IPR&D asset discussed in Note 8, Goodwill and other intangible assets, to the condensed consolidated financial statements, there were no material remeasurements of the fair values of assets and liabilities that are not measured at fair value on a recurring basis.

Summary of the fair values of other financial instruments

Cash equivalents

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

Borrowings

We estimated the fair value of our borrowings (Level 2) by taking into consideration indicative prices obtained from a third-party financial institution that utilizes industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; credit spreads; benchmark yields; foreign currency exchange rates, as applicable; and other observable inputs. As of September 30, 2017 and December 31, 2016, the aggregate fair values of our borrowings were \$39.0 billion and \$36.5 billion, respectively, and the carrying values were \$35.8 billion and \$34.6 billion, respectively.

12. 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 utilize or have utilized certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We do not use derivatives for speculative trading purposes.

Cash flow hedges

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

As of September 30, 2017 and December 31, 2016, we had open foreign currency forward contracts with notional amounts of \$4.0 billion and \$3.4 billion, respectively, and open foreign currency option contracts with notional amounts of \$131 million and \$608 million, respectively. We have designated these foreign currency forward and foreign currency option contracts, which are primarily euro based, as cash flow hedges; and accordingly, we report the effective portions of the unrealized gains and losses on these contracts in AOCI in the Condensed Consolidated Balance Sheets, and we reclassify them to earnings 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, 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, and accordingly, the effective portions of the unrealized gains and losses on these contracts are reported in AOCI in the Condensed Consolidated Balance Sheets and reclassified to earnings in the same periods during which the hedged debt affects earnings.

Edgar Filing: AMGEN INC - Form 10-Q

The notional amounts and interest rates of our cross-currency swaps as of September 30, 2017, were as follows (notional amounts in millions):

Hedged notes	Foreign currency		U.S. dollars	
	Notional amount	Interest rate	Notional amount	Interest rate
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 anticipated issuances of long-term fixed-rate debt, we entered into forward interest rate contracts during the three months ended June 30, 2017. The forward interest rate contracts hedged the variability in cash flows due to changes in the applicable Treasury rate between the time we entered into these contracts and the time the related debt was issued in May 2017. During the three months ended September 30, 2017, we entered into additional forward interest rate contracts with an aggregate notional amount of \$550 million in connection with the anticipated issuance of additional long-term fixed-rate debt. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, were recognized in AOCI in the Condensed Consolidated Balance Sheets and are amortized into earnings over the lives of the associated debt issuances.

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

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Derivatives in cash flow hedging relationships				
Foreign currency contracts	\$(110)	\$(26)	\$(360)	\$(88)
Cross-currency swap contracts	165	67	446	(128)
Forward interest rate contracts	10	(6)	13	(10)
Total	\$65	\$35	\$99	\$(226)

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

	Statements of Income location	Three months ended September 30,		Nine months ended September 30,	
		2017	2016	2017	2016
Derivatives in cash flow hedging relationships					
Foreign currency contracts	Product sales	\$(2)	\$67	\$88	\$242
Cross-currency swap contracts	Interest and other income, net	143	(1)	514	(143)
Forward interest rate contracts	Interest expense, net	(1)	(1)	(1)	(1)
Total		\$140	\$65	\$601	\$98

No portions of our cash flow hedge contracts are excluded from the assessment of hedge effectiveness, and the gains and losses of the ineffective portions of these hedging instruments were not material for the three and nine months ended September 30, 2017 and 2016. As of September 30, 2017, the amounts expected to be reclassified out of AOCI and into earnings during the next 12 months are approximately \$172 million of net losses on our foreign currency and cross-currency swap contracts and approximately \$1 million of losses on forward interest rate contracts.

Fair value hedges

To achieve the desired mix of fixed and floating interest rates on our long-term debt, we entered into interest rate swap contracts that qualified and are designated as fair value hedges. The terms of these interest rate swap contracts correspond to the related hedged debt instruments and effectively convert a fixed interest rate coupon to a floating LIBOR-based coupon over the lives of the respective notes. As of December 31, 2016, we had interest rate swap agreements with aggregate notional amounts of \$6.65 billion that hedge certain of our long-term debt issuances. The contracts have rates that range from three-month LIBOR

plus 0.4% to three-month LIBOR plus 2.0%. During the nine months ended September 30, 2017, we entered into interest rate swap contracts with an aggregate notional amount of \$3.65 billion with respect to our 3.625% 2024 Notes, 3.125% 2025 Notes and 2.60% 2026 Notes. The contracts have rates that range from three-month LIBOR plus 0.3% to three-month LIBOR plus 1.4%. In addition, during the nine months ended September 30, 2017, interest rate swap contracts that had an aggregate notional amount of \$850 million matured. These contracts had rates of three-month LIBOR plus 0.4%.

For derivative instruments that qualify and are designated as fair value hedges, we recognize in current earnings the unrealized gain or loss on the derivative resulting from a change in fair value during the period, as well as the offsetting unrealized loss or gain of the hedged item resulting from a change in fair value during the period attributable to the hedged risk. For the three and nine months ended September 30, 2017, we included unrealized losses of \$17 million and unrealized gains of \$1 million, respectively, on our interest rate swap agreements in the same line item, Interest expense, net, in the Condensed Consolidated Statements of Income, as the offsetting unrealized gains of \$17 million and unrealized losses of \$1 million, respectively, on the related hedged debt. For the three and nine months ended September 30, 2016, we included unrealized losses of \$61 million and unrealized gains of \$137 million, respectively, on our interest rate swap agreements in the same line item, Interest expense, net, in the Condensed Consolidated Statements of Income, as the offsetting unrealized gains of \$61 million and unrealized losses of \$137 million, respectively, on the related hedged debt.

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, 2017 and December 31, 2016, the total notional amounts of these foreign currency forward contracts were \$779 million and \$666 million, respectively.

The location in the Condensed Consolidated Statements of Income and the amounts of gain (loss) 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	Statements of Income location	2017	2016
Foreign currency contracts	Interest and other income, net	\$ (2)	\$ 1
		\$ 12	\$ (33)

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

September 30, 2017	Derivative assets		Derivative liabilities	
	Balance Sheet location	Fair value	Balance Sheet location	Fair value
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other noncurrent assets	\$ 7	Accrued liabilities/ Other noncurrent liabilities	\$ 179
Cross-currency swap contracts	Other noncurrent assets	224	Accrued liabilities/ Other noncurrent liabilities	308
Interest rate swap contracts	Other noncurrent assets	40	Accrued liabilities/ Other noncurrent liabilities	5
Forward interest rate contracts	Other current assets	10	Accrued liabilities	—
Total derivatives designated as hedging instruments		281		492
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	—	Accrued liabilities	—
Total derivatives not designated as hedging instruments		—		—

Total derivatives

\$ 281

\$ 492

22

Edgar Filing: AMGEN INC - Form 10-Q

December 31, 2016	Derivative assets		Derivative liabilities	
	Balance Sheet location	Fair value	Balance Sheet location	Fair value
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other noncurrent assets	\$ 203	Accrued liabilities/ Other noncurrent liabilities	\$ 4
Cross-currency swap contracts	Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	523
Interest rate swap contracts	Other noncurrent assets	41	Accrued liabilities/ Other noncurrent liabilities	7
Total derivatives designated as hedging instruments		244		534
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	—	Accrued liabilities	—
Total derivatives not designated as hedging instruments		—		—
Total derivatives		\$ 244		\$ 534

Our derivative contracts that were in liability positions as of September 30, 2017, 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 the 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 for the nine months ended September 30, 2017 and 2016, are included within Net cash provided by operating activities in the Condensed Consolidated Statements of Cash Flows.

13. 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, 2016, 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 Note; 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, 2016; and in Notes 12 and 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2017 and June 30, 2017, 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 range from cases brought by a single plaintiff to a class action with thousands of putative class members. These legal proceedings, as well as other matters, involve various aspects of our business and a variety of claims—including but not limited to patent infringement, marketing, pricing and trade practices and securities law—some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing, in Note 18, Contingencies and commitments, to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2016, or in Notes 12 or 13, Contingencies and commitments, to our condensed

consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2017 and June 30, 2017, 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 faced by us 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 our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2016, or in Notes 12 or 13, Contingencies and

commitments, to our condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2017 and June 30, 2017, respectively, have progressed sufficiently through discovery and/or development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these 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:

PCSK9 Antibody Patent Litigation

U.S. Patent Litigation—Sanofi/Regeneron

On October 5, 2017, the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court) reversed-in-part the judgment of the U.S. District Court for Delaware (the Delaware District Court) and remanded for a new trial two of defendants' patent validity defenses (failure to meet the law's requirements for patentability of written description and enablement of the claimed inventions) and affirmed the Delaware District Court's judgment of infringement of claims 2, 7, 9, 15, 19 and 29 of U.S. Patent No. 8,829,165 and claim 7 of U.S. Patent No. 8,859,741 and patent validity on the defendants' third patent validity defense (finding that the claimed inventions were not obvious to a person of ordinary skill in the field of the patents). The Federal Circuit Court also vacated and remanded for further consideration by the Delaware District Court the permanent injunction granted by the Delaware District Court prohibiting the infringing manufacture, use, sale, offer for sale or import of alirocumab in the United States.

Sensipar[®] (cinacalcet) Litigation

Sensipar[®] Abbreviated New Drug Application (ANDA) Patent Litigation

As previously disclosed, Amgen has filed 18 separate lawsuits against defendants for infringement of our U.S. Patent No. 9,375,405 (the '405 Patent), and 15 of these 18 lawsuits have been consolidated by the Delaware District Court. Amgen filed and the court signed stipulated dismissals of the lawsuits against defendants Apotex Inc. and Apotex Corp. (collectively, Apotex), on September 11, 2017, and against defendants Micro Labs Ltd. and Micro Labs USA, Inc., on September 20, 2017. On September 21, 2017, the Delaware District Court signed a consent judgment filed by Amgen and Breckenridge Pharmaceutical, Inc. (Breckenridge) stipulating to entry of judgment of infringement and validity of the '405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of, or distribution into the United States of the Breckenridge cinacalcet product during the term of the '405 Patent unless specifically authorized pursuant to the confidential settlement agreement. In addition, during September 2017, defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. filed motions for judgment on the pleadings and to dismiss the complaint pending against them and Amgen filed oppositions to such motions.

Sensipar[®] Pediatric Exclusivity Litigation

As previously disclosed, Amgen filed a lawsuit in the U.S. District Court for the District of Columbia seeking effectively to reverse the U.S. Food and Drug Administration's (FDA's) May 22, 2017 rejection of Amgen's request for pediatric exclusivity for cinacalcet hydrochloride (Sensipar[®]/ Mimpara[®]). On August 10, 2017, the court entered an expedited scheduling order for Amgen and the FDA to file cross-motions for summary judgment and a hearing on such motions is set for December 15, 2017. Amgen filed its motion for summary judgment on October 18, 2017.

KYPROLIS[®] (carfilzomib) ANDA Patent Litigation

As previously disclosed, the Delaware District Court consolidated ten separate lawsuits filed by our subsidiary Onyx Therapeutics, Inc. (Onyx Therapeutics) against defendants for infringement of certain of our patents. On August 17, 2017, Onyx Therapeutics filed an additional lawsuit in the Delaware District Court against InnoPharma, Inc. for infringement of U.S. Patent Nos. 7,232,818 (the '818 Patent); 7,491,704 (the '704 Patent); 8,129,346 (the '346 Patent); 8,207,125 (the '125 Patent); 8,207,126 (the '126 Patent); and 8,207,127 (the '127 Patent). Onyx Therapeutics filed two additional lawsuits in the Delaware District Court against Apotex, on August 24, 2017, and Qilu Pharma, Inc. and Qilu Pharmaceutical Co. Ltd. (collectively Qilu), on August 30, 2017, for infringement of the '818, '704, '346, '125, '126, '127 Patents and U.S. Patent Nos. 7,417,042 and 8,207,297. In each lawsuit, Onyx Therapeutics seeks an order of the Delaware District Court making any FDA approval of the defendant's ANDA effective no earlier than the expiration of the applicable patents. On September 14, 2017, the Delaware District Court consolidated these three additional lawsuits for purposes of discovery into the existing consolidated case. Responses to these new complaints have been filed by InnoPharma, Inc., Apotex and Qilu alleging invalidity and, in certain instances, non-infringement of the

patents. On September 20, 2017, by joint stipulation of the parties, Teva Pharmaceutical Industries Ltd. was dismissed from one of the previously-filed lawsuits, leaving Teva Pharmaceuticals USA, Inc. as the remaining defendant in that litigation.

Amgen Biosimilars Litigation

AMJEVITA™(adalimumab-atto) Patent Litigation

On September 27, 2017, Amgen and AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively, AbbVie), entered into a global settlement and license agreement. Under the terms of the agreement, AbbVie will grant patent licenses for the use and sale of Amgen's AMJEVITA™/AMGEVITA™(a biosimilar to AbbVie's HUMIRA® (adalimumab)) worldwide, on a country-by-country basis, and the companies have agreed to dismiss pending patent litigation. The agreement allows Amgen to begin marketing AMJEVITA™/AMGEVITA™ in the various countries at specified dates. On September 28, 2017, the Delaware District Court entered a stipulation to dismiss all claims and counterclaims of this litigation.

MVASI™(bevacizumab-awwb) Patent Litigation

On October 6, 2017, Amgen filed a lawsuit in the U.S. District Court for the Central District of California against Genentech, Inc. (Genentech) and the City of Hope seeking a declaratory judgment that 27 patents listed by Genentech in the Biologics Price Competition and Innovation Act (BPCIA) exchange are invalid, unenforceable and not infringed by MVASI™, formerly ABP 215, Amgen's biosimilar of Avastin® (bevacizumab). On October 7, 2017, Genentech and City of Hope filed a separate lawsuit in the Delaware District Court alleging Amgen's infringement of 24 of the 27 patents which are the subject of the lawsuit in California. On October 10, 2017, Amgen filed a motion to transfer Genentech's first Delaware lawsuit to California. On October 18, 2017, Genentech and City of Hope filed a second lawsuit in the Delaware District Court alleging Amgen's infringement of 25 of the same 27 patents, and on October 23, 2017, Amgen filed a motion to transfer Genentech's second Delaware lawsuit to California.

Other Biosimilars Patent Litigation

We have filed a number of lawsuits against manufacturers of products that purport to be biosimilars of certain of our products. In each case, our complaint alleges that the manufacturer's actions infringe certain patents we hold and may also allege that the manufacturer has failed to comply with certain provisions of the BPCIA. Additionally, a number of manufacturers have challenged the validity of our applicable patents and/or contended that such patents are not infringed by such manufacturers' biosimilar products.

Filgrastim/Pegfilgrastim Litigation

Sandoz (pegfilgrastim). Trial for this patent infringement case is scheduled for March 26, 2018.

Sandoz (filgrastim). On September 13, 2017, by joint stipulation of the parties, the U.S. District Court for the Northern District of California (the California Northern District Court) dismissed from the case the parties' respective claims and counterclaims related to U.S. Patent No. 6,162,427. Trial for the remaining patent infringement claim is scheduled for March 26, 2018.

As previously disclosed, Sandoz filed a request of the Federal Circuit Court to remand the BPCIA litigation to the California Northern District Court to allow that court to address the questions of California law. On August 28, 2017, at the request of the Federal Circuit Court, the parties filed supplemental briefs stating their respective positions on the appropriate action to be taken by the California Northern District Court on remand.

Apotex (pegfilgrastim/filgrastim). On October 3, 2017, the Federal Circuit Court heard argument on Amgen's appeal of the judgment of the U.S. District Court for the Southern District of Florida finding that Apotex's process of manufacturing its filgrastim and pegfilgrastim products do not infringe our U.S. Patent No. 8,952,138.

Coherus (pegfilgrastim). As previously disclosed, Amgen filed a lawsuit in the Delaware District Court against Coherus BioSciences, Inc. (Coherus) for infringement of our U.S. Patent No. 8,273,707 (the '707 Patent). A claim construction hearing is scheduled for June 25, 2018, and trial is scheduled to commence on September 16, 2019.

Mylan (pegfilgrastim). On September 22, 2017, Amgen and Amgen Manufacturing, Limited (AML) filed a lawsuit in the District Court for the Western District of Pennsylvania against Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. (collectively, Mylan) for infringement of our '707 Patent and U.S. Patent No. 9,643,997 (the '997 Patent). This lawsuit stems from Mylan's submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen's Neulasta® (pegfilgrastim) under the BPCIA. By their complaint, Amgen and AML seek, among other remedies, an injunction prohibiting Mylan from infringing the '707 and '997 Patents.

Etanercept Litigation

Sandoz (etanercept). On September 14, 2017, Amgen filed a motion for summary judgment that Sandoz infringed claim 1 of U.S. Patent No. 8,722,631 and, on October 23, 2017, Sandoz filed its brief in opposition to the motion.

Coherus (etanercept). On August 4, 2017, Coherus filed a petition seeking to institute inter partes review (IPR) proceedings before the United States Patent and Trademark Office's Patent Trial Appeal Board (PTAB) to challenge the patentability of each claim of U.S. Patent No. 8,163,522 (the '522 Patent). On September 7, 2017, Coherus filed a second IPR petition, seeking to institute PTAB proceedings to challenge the patentability of each claim of U.S. Patent No. 8,063,182 (the '182 Patent). Both the '522 Patent and the '182 Patent relate to Enbrel (etanercept) and are exclusively licensed to our subsidiary Immunex Corporation by Hoffmann-La Roche Inc. The deadlines to file a patent owner preliminary response to the Coherus IPR petition regarding the '522 Patent and the '182 Patent are December 13, 2017 and December 26, 2017, respectively, and the deadlines expected for the PTAB to render a decision regarding whether to institute PTAB trial proceedings on the '522 Patent and the '182 Patent are March 13, 2018 and March 26, 2018, respectively.

Epoetin Alfa Litigation

Hospira (epoetin alfa). On September 7, 2017, the Delaware District Court denied a motion for summary judgment of non-infringement of the patents-in-suit by Hospira, Inc. (Hospira), a subsidiary of Pfizer. On September 22, 2017, after a five day jury trial, the jury returned a verdict finding U.S. Patent No. 5,856,298 (the '298 Patent) valid and infringed by Hospira and U.S. Patent No. 5,756,349 (the '349 Patent) not infringed. The jury awarded Amgen \$70 million in damages for Hospira's infringement. On October 23, 2017, Amgen moved for judgment as a matter of law that Hospira infringed the '349 Patent or, in the alternative, for a new trial on infringement of the '349 Patent. In addition, on October 23, 2017, Hospira moved for judgment as a matter of law of non-infringement and invalidity of the '298 Patent or, in the alternative, for reduction of the damage award or a new trial on the '298 Patent.

State Derivative Litigation

On July 3, 2017, defendants in this state stockholder derivative lawsuit filed demurrers seeking dismissal of all claims. A hearing on the demurrers was held on October 6, 2017.

ERISA Litigation

On August 10, 2017, the remaining plaintiff voluntarily dismissed his appeal of the settlement reached in this case.

U.S. Attorney's Office for the District of Massachusetts - Patient Assistance Investigation

Amgen, together with other companies in our industry, has received inquiries from the U.S. Attorney's Office for the District of Massachusetts relating to support of charitable 501(c)(3) organizations that provide financial assistance to Medicare patients. Amgen is cooperating with this ongoing inquiry.

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, 2016, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2017 and June 30, 2017. 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 U.S. Securities and Exchange Commission (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," "see," "should," "may," "assume" and "continue," as well as variations of such words and similar expressions, are intended to identify such forward-looking statements. These statements are not guarantees of future performance, and they involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in 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 forecast by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, 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 committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer 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 therapeutics for oncology/hematology, inflammation, nephrology, bone health and cardiovascular disease. Our principal products are ENBREL, Neulasta®, Aranesp® (darbepoetin alfa), Prolia® (denosumab), Sensipar®/Mimpara®, XGEVA® (denosumab) and EPOGEN® (epoetin alfa). We market several other products as well, including KYPROLIS®, Vectibix® (panitumumab), Nplate® (romiplostim), NEUPOGEN® (filgrastim), Repatha® (evolocumab), BLINCYTO® (blinatumomab), IMLYGIC®, Corlanor® (ivabradine) and Parsabiv® (etelcalcetide).

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, 2017. 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, 2016, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2017 and June 30, 2017.

Products/Pipeline

Bone Health

Prolia®

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

Cardiovascular

Repatha®

In July 2017, we announced that the FDA granted priority review for the sBLA for Repatha® to include risk reduction of major cardiovascular events in the Repatha® label. The FDA has set a PDUFA target action date of December 2, 2017.

In October 2017, the Federal Circuit Court issued a ruling that reversed the Delaware District Court's decision which prohibited Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc. from infringing two patents that we hold for Repatha® by manufacturing, using, selling, offering for sale or importing alirocumab in the United States. See Note 13, Contingencies and commitments, to the condensed consolidated financial statements.

In October 2017, we announced that a phase 3 study of Repatha® on top of maximally tolerated statin therapy in type 2 diabetic patients with hypercholesterolemia met its co-primary endpoints of the percent reduction from baseline in LDL-C at week 12 and the mean percent reduction from baseline in LDL-C at weeks 10 and 12. No new safety findings were identified.

Oncology/Hematology

Aranesp®

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

KYPROLIS®

In August 2017, we announced that the FDA accepted for review a supplemental New Drug Application based on the overall survival data from the phase 3 head-to-head ENDEAVOR (Randomized, Open Label, Phase 3 Study of Carfilzomib Plus Dexamethasone Vs Bortezomib Plus Dexamethasone in Patients With Relapsed Multiple Myeloma) study demonstrating KYPROLIS® and dexamethasone (Kd) reduced the risk of death by 21 percent and increased overall survival by 7.6 months versus Velcade® (bortezomib) and dexamethasone (Vd) in patients with relapsed or refractory multiple myeloma. The FDA has set a PDUFA target action date of April 30, 2018.

In October 2017, we announced top-line results of the phase 3 A.R.R.O.W. (Randomized, Open-label, Phase 3 Study in Subjects with Relapsed and Refractory Multiple Myeloma Receiving Carfilzomib in Combination with Dexamethasone, Comparing Once-Weekly versus Twice-weekly Carfilzomib Dosing) study, which showed KYPROLIS® administered once-weekly at the 70 mg/m² dose with dexamethasone allowed relapsed and refractory multiple myeloma patients to live 3.6 months longer without their disease worsening than KYPROLIS® administered twice-weekly at the 27 mg/m² dose with dexamethasone. The overall safety profile of the once-weekly KYPROLIS® regimen was comparable to that of the twice-weekly regimen.

Nephrology

Sensipar®/Mimpara®

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

Biosimilars

ABP 980

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

MVASI™

In September 2017, we and Allergan announced that the FDA approved MVASI™ for all eligible indications of the reference product, Avastin®. MVASI™ is the first anti-cancer biosimilar, as well as the first bevacizumab biosimilar, approved by the FDA. MVASI™ is approved for the treatment of five types of cancer.

AMJEVITA[™]/AMGEVITA[™]

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

Selected financial information

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

	Three months ended			Nine months ended		
	September 30, 2017	2016	Change	September 30, 2017	2016	Change
Product sales:						
U.S.	\$4,297	\$4,383	(2)%	\$12,778	\$12,819	— %
Rest of the world (ROW)	1,156	1,133	2 %	3,448	3,410	1 %
Total product sales	5,453	5,516	(1)%	16,226	16,229	— %
Other revenues	320	295	8 %	821	797	3 %
Total revenues	\$5,773	\$5,811	(1)%	\$17,047	\$17,026	— %
Operating expenses	\$3,334	\$3,284	2 %	\$9,319	\$9,717	(4)%
Operating income	\$2,439	\$2,527	(3)%	\$7,728	\$7,309	6 %
Net income	\$2,021	\$2,017	— %	\$6,243	\$5,787	8 %
Diluted EPS	\$2.76	\$2.68	3 %	\$8.46	\$7.63	11 %
Diluted shares	733	753	(3)%	738	758	(3)%

Global product sales decreased one percent for the three months ended September 30, 2017, and were flat for the nine months ended September 30, 2017.

The increase in other revenues for the three months ended September 30, 2017, was driven primarily by higher Ibrance[®] (palbociclib) royalty income. The increase in other revenues for the nine months ended September 30, 2017, was driven primarily by higher Ibrance[®] royalty income, offset partially by lower milestone payments received. The increase in operating expenses for the three months ended September 30, 2017, was driven primarily by net charges associated with the discontinuance of the internal development of AMG 899, offset partially by the expiration of ENBREL residual royalty payments and lower external business development expenses. The decrease in operating expenses for the nine months ended September 30, 2017, was driven primarily by the expiration of ENBREL residual royalty payments and lower spending required to support certain later-stage clinical programs, offset partially by net charges associated with the discontinuance of the internal development of AMG 899. All expense categories benefited from our continued transformation and process improvement efforts.

Net income for the three months ended September 30, 2017, was relatively flat. The increase in diluted EPS for the three months ended September 30, 2017, was driven primarily by lower weighted-average diluted shares. The increases in net income and diluted EPS for the nine months ended September 30, 2017, were driven primarily by higher operating margins.

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, 2017 and 2016.

Results of operations

Product sales

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

	Three months ended			Nine months ended		
	September 30,			September 30,		
	2017	2016	Change	2017	2016	Change
ENBREL	\$1,363	\$1,452	(6)%	\$4,010	\$4,321	(7)%
Neulasta®	1,123	1,200	(6)%	3,420	3,532	(3)%
Aranesp®	516	531	(3)%	1,562	1,567	— %
Prolia®	464	379	22 %	1,394	1,172	19 %
Sensipar®/Mimpara®	457	415	10 %	1,305	1,171	11 %
XGEVA®	387	394	(2)%	1,184	1,153	3 %
EPOGEN®	264	335	(21)%	826	966	(14)%
Other products	879	810	9 %	2,525	2,347	8 %
Total product sales	\$5,453	\$5,516	(1)%	\$16,226	\$16,229	— %

Future sales of our products are influenced by a number of factors, some of which may impact sales of certain of our products more significantly than others. Such factors are discussed below and in the following sections of our Annual Report on Form 10-K for the year ended December 31, 2016: (i) Overview, Item 1. Business—Marketing, Distribution and Selected Marketed Products, (ii) Item 1A. Risk Factors and (iii) Item 7. Results of Operations—Product Sales; and in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2017 and June 30, 2017, in Part II, Item 1A. Risk Factors.

ENBREL

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

	Three months ended			Nine months ended		
	September 30,			September 30,		
	2017	2016	Change	2017	2016	Change
ENBREL — U.S.	\$1,309	\$1,388	(6)%	\$3,838	\$4,137	(7)%
ENBREL — Canada	54	64	(16)%	172	184	(7)%
Total ENBREL	\$1,363	\$1,452	(6)%	\$4,010	\$4,321	(7)%

The decrease in ENBREL sales for the three months ended September 30, 2017, was driven primarily by a decline in unit demand and lower net selling price, offset partially by favorable changes in inventory.

The decrease in ENBREL sales for the nine months ended September 30, 2017, was driven primarily by a decline in unit demand, offset partially by favorable changes in inventory.

For the full year 2017, we expect a decline in unit demand and a slight decline in net selling price, both of which we expect to continue in 2018.

Neulasta®

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

	Three months ended			Nine months ended		
	September 30,			September 30,		
	2017	2016	Change	2017	2016	Change
Neulasta®— U.S.	\$977	\$1,024	(5)%	\$2,962	\$2,982	(1)%
Neulasta®— ROW	46	176	(17)%	458	550	(17)%
Total Neulasta®	\$1,123	\$1,200	(6)%	\$3,420	\$3,532	(3)%

The decrease in global Neulasta® sales for the three months ended September 30, 2017, was driven primarily by a decline in unit demand.

The decrease in global Neulasta® sales for the nine months ended September 30, 2017, was driven primarily by a decline in unit demand, offset partially by an increase in net selling price and favorable changes in accounting estimates.

As of September 30, 2017, utilization of the Neulasta® Onpro® kit continued to grow in the United States.

We expect to face competition in the United States, which over time may have a material adverse impact on future sales of Neulasta®. Multiple companies have announced applications to the FDA for proposed biosimilar versions of Neulasta®. Three of these companies have announced receipt of Complete Response Letters from the FDA regarding their applications.

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

Aranesp®

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

	Three months ended September 30, 2017			Nine months ended September 30, 2017		
	2017	2016	Change	2017	2016	Change
Aranesp® — U.S.	\$285	\$275	4 %	\$851	\$796	7 %
Aranesp® — ROW	\$31	256	(10) %	711	771	(8) %
Total Aranesp®	\$516	\$531	(3) %	\$1,562	\$1,567	— %

The decrease in global Aranesp® sales for the three months ended September 30, 2017, was driven primarily by unfavorable changes in foreign currency exchange rates and lower unit demand.

The decrease in global Aranesp® sales for the nine months ended September 30, 2017, was driven primarily by unfavorable changes in foreign currency exchange rates, offset partially by a shift by some U.S. dialysis customers from EPOGEN® to Aranesp®.

Aranesp® may face competition in the United States from branded products, as well as proposed short-acting biosimilars.

Prolia®

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

	Three months ended September 30, 2017			Nine months ended September 30, 2017		
	2017	2016	Change	2017	2016	Change
Prolia® — U.S.	\$298	\$249	20 %	\$903	\$756	19 %
Prolia® — ROW	\$66	130	28 %	491	416	18 %
Total Prolia®	\$464	\$379	22 %	\$1,394	\$1,172	19 %

The increases in global Prolia® sales for the three and nine months ended September 30, 2017, 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, 2017			Nine months ended September 30, 2017		
	2017	2016	Change	2017	2016	Change

Edgar Filing: AMGEN INC - Form 10-Q

Sensipar [®] — U.S.	\$373	\$329	13 %	\$1,052	\$910	16 %
Sensipar [®] /Mimpara [®] — ROW	84	86	(2)%	253	261	(3)%
Total Sensipar [®] /Mimpara [®]	\$457	\$415	10 %	\$1,305	\$1,171	11 %

The increases in global Sensipar[®]/Mimpara[®] sales for the three and nine months ended September 30, 2017, were driven primarily by an increase in net selling price.

Our U.S. composition of matter patent relating to Sensipar[®], a small molecule, expires in March 2018. We are also involved in a number of litigation matters related to Sensipar[®]. See Note 13, Contingencies and commitments, to the condensed consolidated financial statements.

XGEVA[®]

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

	Three months ended September 30,			Nine months ended September 30,		
	2017	2016	Change	2017	2016	Change
XGEVA [®] — U.S.	\$282	\$296	(5)%	\$872	\$842	4 %
XGEVA [®] — ROW	5	98	7 %	312	311	— %
Total XGEVA [®]	\$387	\$394	(2)%	\$1,184	\$1,153	3 %

The decrease in global XGEVA[®] sales for the three months ended September 30, 2017, was driven primarily by lower unit demand, offset partially by an increase in net selling price.

The increase in global XGEVA[®] sales for the nine months ended September 30, 2017, was driven primarily by higher unit demand and an increase in net selling price, offset partially by unfavorable changes in foreign exchange rates.

EPOGEN[®]

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

	Three months ended September 30,			Nine months ended September 30,		
	2017	2016	Change	2017	2016	Change
EPOGEN [®] — U.S.	\$264	\$335	(21)%	\$826	\$966	(14)%

The decrease in EPOGEN[®] sales for the three months ended September 30, 2017, was driven primarily by a decrease in net selling price due to a negotiated contract with DaVita Inc., as well as unfavorable changes in inventory.

The decrease in EPOGEN[®] sales for the nine months ended September 30, 2017, was driven primarily by a decrease in net selling price due to a negotiated contract with DaVita Inc.

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[®]. One company has announced receipt of a Complete Response Letter from the FDA regarding its application.

Other products

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

	Three months ended September 30,			Nine months ended September 30,		
	2017	2016	Change	2017	2016	Change
KYPROLIS® — U.S.	\$135	\$140	(4)%	\$412	\$411	— %
KYPROLIS® — ROW	72	43	67 %	196	98	100 %
Vectibix® — U.S.	65	64	2 %	188	172	9 %
Vectibix® — ROW	103	100	3 %	295	296	— %
Nplate® — U.S.	96	92	4 %	292	262	11 %
Nplate® — ROW	63	59	7 %	185	172	8 %
NEUPOGEN® — U.S.	96	127	(24)%	287	418	(31)%
NEUPOGEN® — ROW	42	56	(25)%	136	174	(22)%
Repatha® — U.S.	62	31	100 %	155	65	*
Repatha® — ROW	27	9	*	66	18	*
BLINCYTO®—U.S.	34	19	79 %	85	61	39 %
BLINCYTO®—ROW	18	10	80 %	44	25	76 %
Other — U.S.	21	14	50 %	55	41	34 %
Other — ROW	45	46	(2)%	129	134	(4)%
Total other products	\$879	\$810	9 %	\$2,525	\$2,347	8 %
Total U.S. — other products	\$509	\$487	5 %	\$1,474	\$1,430	3 %
Total ROW — other products	\$370	\$323	15 %	\$1,051	\$917	15 %
Total other products	\$879	\$810	9 %	\$2,525	\$2,347	8 %

* 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,		
	2017	2016	Change	2017	2016	Change
Cost of sales	\$990	\$1,027	(4)%	\$3,010	\$3,095	(3)%
% of product sales	18.2 %	18.6 %		18.6 %	19.1 %	
% of total revenues	17.1 %	17.7 %		17.7 %	18.2 %	
Research and development	\$877	\$990	(11)%	\$2,519	\$2,762	(9)%
% of product sales	16.1 %	17.9 %		15.5 %	17.0 %	
% of total revenues	15.2 %	17.0 %		14.8 %	16.2 %	
Selling, general and administrative	\$1,170	\$1,244	(6)%	\$3,443	\$3,739	(8)%
% of product sales	21.5 %	22.6 %		21.2 %	23.0 %	
% of total revenues	20.3 %	21.4 %		20.2 %	22.0 %	
Other	\$297	\$23	*	\$347	\$121	*

* Change in excess of 100%

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 continue to estimate will result in pre-tax accounting charges in the range of \$800 million to \$900 million. As of September 30, 2017, restructuring costs incurred to date were \$771 million. The charges that were recorded related to the restructuring during the three and nine months ended September 30, 2017, were not significant. Since 2014, we have realized approximately \$1.3 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.

Puerto Rico operations

Since Hurricane Maria struck Puerto Rico in September 2017, we have been providing support to our staff members and the local community while implementing business continuity plans and restoring manufacturing operations at our site in Juncos. All of our staff in Puerto Rico have been accounted for and nearly all are back at work. Our drug substance manufacturing and packaging plants are fully operational and we expect to resume formulation/filling and small molecule commercial production by the end of October 2017. We continue to provide an uninterrupted supply of medicines for patients around the world.

We incurred \$67 million of pre-tax expenses during the three months ended September 30, 2017, related to Hurricane Maria. In the three months ending December 31, 2017, we expect additional pre-tax expenses in the range of \$75 million to \$100 million. At this time, we do not expect significant pre-tax expenses in 2018. These estimates do not include possible insurance recoveries.

Cost of sales

Cost of sales decreased to 17.1% of total revenues for the three months ended September 30, 2017, driven primarily by a reduction in amortization of intangible assets and manufacturing efficiencies, offset partially by expenses related to Hurricane Maria.

Cost of sales decreased to 17.7% of total revenues for the nine months ended September 30, 2017, driven primarily by manufacturing efficiencies.

The excise tax imposed by the U.S. territory of Puerto Rico on the gross intercompany purchase price of goods and services from our manufacturer in Puerto Rico (Puerto Rico excise tax) is recorded as a cost of sales expense.

Excluding the impact of the Puerto Rico excise tax, cost of sales would have been 15.6% and 16.1% of total revenues for the three and nine months ended September 30, 2017, respectively, compared with 16.1% and 16.5% for the corresponding periods of the prior year. See Note 3, Income taxes, to the condensed consolidated financial statements for further discussion of the Puerto Rico excise tax.

Research and development

The decrease in R&D expenses for the three months ended September 30, 2017, was driven primarily by lower external business development expense in Discovery Research and Translational Sciences (DRTS) and lower spending required to support certain later-stage clinical programs. The costs associated with DRTS and later-stage clinical programs decreased by \$73 million and \$44 million, respectively. The costs associated with marketed products were relatively unchanged.

The decrease in R&D expenses for the nine months ended September 30, 2017, was driven primarily by lower spending required to support certain later-stage clinical programs and lower external business development expense in DRTS. The costs associated with our later-stage clinical programs, DRTS and marketed products decreased by \$116 million, \$73 million and \$54 million, respectively.

Selling, general and administrative

The decrease in Selling, general and administrative (SG&A) expenses for the three months ended September 30, 2017, was driven primarily by the expiration of ENBREL residual royalty payments on October 31, 2016, offset partially by investments in product launches.

The decrease in SG&A expenses for the nine months ended September 30, 2017, was driven primarily by the expiration of ENBREL residual royalty payments on October 31, 2016, as well as a charge related to an acquisition in

the three months ended March 31, 2016, offset partially by investments in product launches.

34

Other

Other operating expenses for the three and nine months ended September 30, 2017, included net charges associated with the discontinuance of the internal development of AMG 899 and certain net charges related to our restructuring plan.

Other operating expenses for the three months ended September 30, 2016, included the impairment of a non-key contract asset acquired in a prior year business combination. Other operating expenses for the nine months ended September 30, 2016, included legal-proceeding charges of \$105 million.

Non-operating expense/income and income taxes

Non-operating expense/income and income taxes were as follows (dollar amounts in millions):

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Interest expense, net	\$325	\$325	\$972	\$932
Interest and other income, net	\$267	\$216	\$627	\$503
Provision for income taxes	\$360	\$401	\$1,140	\$1,093
Effective tax rate	15.1 %	16.6 %	15.4 %	15.9 %

Interest expense, net

The increase in Interest expense, net, for the nine months ended September 30, 2017, was due primarily to a higher average amount of debt outstanding.

Interest and other income, net

The increase in Interest and other income, net, for the three and nine months ended September 30, 2017, was due primarily to higher interest income that resulted from higher average investment balances.

Income taxes

The decrease in our effective tax rate for the three months ended September 30, 2017, was due primarily to favorable tax impacts of changes in the jurisdictional mix of income and expenses, as well as discrete benefits associated with the impairment of our AMG 899 asset and the related release of contingent consideration liabilities connected with the acquisition of Dezima, offset partially by adjustments to certain federal tax credits and deductions.

The decrease in our effective tax rate for the nine months ended September 30, 2017, was due primarily to favorable tax impacts of changes in the jurisdictional mix of income and expenses, as well as discrete benefits associated with the effective settlement of certain state and federal tax matters, offset partially by lower tax benefits from share-based compensation payments and adjustments to certain federal tax credits and deductions.

Excluding the impact of the Puerto Rico excise tax, our effective tax rate for the three and nine months ended September 30, 2017, would have been 17.8% and 18.2%, respectively, compared with 19.4% and 18.8%, respectively, for the corresponding periods of the prior year.

As previously disclosed, we received a RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We are in discussions with the IRS examination team and understand that the RAR may be modified. 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 3, Income taxes, to the condensed consolidated financial statements for further discussion.

Financial condition, liquidity and capital resources

Selected financial data were as follows (in millions):

	September 30, 2017	December 31, 2016
Cash, cash equivalents and marketable securities	\$ 41,351	\$ 38,085
Total assets	\$ 80,331	\$ 77,626
Short-term borrowings and current portion of long-term debt	\$ 1,999	\$ 4,403
Long-term debt	\$ 33,777	\$ 30,193
Stockholders' equity	\$ 32,229	\$ 29,875

We intend to continue to return capital to stockholders through the payment of cash dividends and stock repurchases reflecting our confidence in the future cash flows of our business. The timing and amounts 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 amounts of stock repurchases may also be affected by the stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include private block purchases, tender offers and market transactions.

In July 2017, March 2017 and December 2016, the Board of Directors declared quarterly cash dividends of \$1.15 per share of common stock, which were paid on September 8, June 8 and March 8, 2017, respectively. In October 2017, the Board of Directors declared a quarterly cash dividend of \$1.15 per share of common stock, which will be paid on December 8, 2017.

We have also returned capital to stockholders through our stock repurchase program. During the nine months ended September 30, 2017, we repurchased \$2.3 billion of our stock and paid \$2.4 billion in cash during the period. During the nine months ended September 30, 2016, we repurchased \$2.0 billion of our stock. As of September 30, 2017, \$1.7 billion remained available under the Board of Directors-approved stock repurchase program. In October 2017, the Board of Directors authorized an increase that resulted in a total of \$5.0 billion available under the stock repurchase program.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or our syndicated credit facilities and access to other domestic and foreign debt markets and equity markets. During the second quarter of 2017, we began borrowing under our \$2.5 billion commercial paper program and as of September 30, 2017, we had \$1.5 billion outstanding under this program.

With respect to our U.S. operations, we believe that existing funds intended for use in the United States; cash generated from our U.S. operations, including intercompany payments and receipts; and existing sources of and access to financing (collectively, U.S. funds) are adequate to continue meeting our U.S. obligations, including our plans to pay dividends and repurchase stock with U.S. funds, for the foreseeable future. See our Annual Report on Form 10-K for the year ended December 31, 2016, Part I, Item 1A. Risk Factors—Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Of our cash, cash equivalents and marketable securities balances totaling \$41.4 billion as of September 30, 2017, approximately \$38.9 billion was generated from operations in foreign tax jurisdictions and is intended to be invested indefinitely outside the United States. Under current tax laws, if these funds were repatriated for use in our U.S. operations, we would be required to pay additional income taxes at the tax rates then in effect.

Certain of our financing arrangements contain non-financial covenants. In addition, our revolving credit agreement includes a financial covenant with respect to the level of our borrowings in relation to our equity, as defined. We were in compliance with all applicable covenants under these arrangements as of September 30, 2017.

Cash flows

Our cash flow activities were as follows (in millions):

	Nine months ended September 30,	
	2017	2016
Net cash provided by operating activities	\$8,165	\$7,254
Net cash used in investing activities	\$(3,946)	\$(7,436)
Net cash used in financing activities	\$(4,460)	\$(477)

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, 2017, increased compared with the same period in the prior year due primarily to an increase in net income, offset partially by the timing of payments to taxing authorities.

Investing

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. Cash used in investing activities during the nine months ended September 30, 2016, was due primarily to net activity related to marketable securities of \$6.7 billion and capital expenditures of \$511 million. Capital expenditures during the nine months ended September 30, 2017 and 2016, were associated primarily with manufacturing capacity expansions in various locations, as well as other site developments. We currently estimate 2017 spending on capital projects and equipment to be approximately \$700 million.

Financing

Cash used in financing activities during the nine months ended September 30, 2017, was due primarily to 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 issuances, of \$920 million, offset partially by net proceeds from the issuance of commercial paper of \$1.5 billion. Cash used in financing activities during the nine months ended September 30, 2016, was due primarily to the payment of dividends of \$2.3 billion and repurchases of our common stock of \$2.0 billion, offset partially by proceeds from the issuance of long-term debt, net of repayments, of \$4.0 billion. See Note 9, Financing arrangements, and Note 10, 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, actual results could differ materially from those estimates under different assumptions or conditions. 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, 2016. There were no material changes to our critical accounting policies during the nine months ended September 30, 2017.

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, 2016, and is incorporated herein by reference. Except as discussed below, no material changes occurred during the nine months ended September 30, 2017, 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, 2016.

Interest rate sensitive financial instruments

To achieve a desired mix of fixed- and floating-interest-rate debt, we entered into interest rate swap contracts with an aggregate notional amount of \$3.65 billion during the nine months ended September 30, 2017. In addition, we had interest rate swap contracts with an aggregate notional amount of \$850 million mature during the nine months ended September 30, 2017. As of September 30, 2017, interest rate swap contracts with an aggregate notional amount of \$9.45 billion were outstanding. These interest rate swap contracts effectively converted a fixed-interest-rate coupon to

a floating-rate LIBOR-based coupon over the life of the

37

respective note. A hypothetical 100-basis-point increase in interest rates relative to interest rates at September 30, 2017, would have resulted in reductions in fair values of approximately \$450 million on our interest rate swap contracts on this date and would not result in a material effect on the related income in the ensuing year. The analysis for the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair values of debt that these interest rate sensitive interests were designed to offset.

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, 2017.

Management determined that, as of September 30, 2017, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

See Note 13, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the periods ended September 30, 2017 and June 30, 2017, and Note 12, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the period ended March 31, 2017, 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, 2016.

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 they 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, 2016, 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. Risk Factors, of our Annual Report, on Form 10-K for the year ended December 31, 2016, and in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2017 and June 30, 2017, provide additional disclosure for these supplemental risks and are incorporated herein by reference.

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

We currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and substantially all of our clinical manufacturing activities at our facility in Thousand Oaks, California. The global supply of our products and product candidates for commercial sales and for use in our clinical trials is significantly dependent on the uninterrupted and efficient operation of these facilities. See our Annual Report on Form 10-K for the year ended December 31, 2016, Part I, Item 1A. Risk Factors—Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

In late September 2017, Hurricane Maria, a Category 4 storm, made landfall on the island of Puerto Rico. The hurricane destroyed residential and commercial buildings, agriculture, communications networks and most of Puerto Rico's electric grid. The critical manufacturing areas of our commercial manufacturing facility were not significantly impacted by the storm, and we are in the process of resuming our full manufacturing operations. Puerto Rico officials suggest that it may be months before electrical service is restored to much of the island, and as a result our facility is operating with electrical power from back-up diesel-powered generators. We are currently receiving regular deliveries of diesel fuel under pre-arranged contracts. In addition, supplies of medical-grade oxygen and nitrogen used in biopharmaceutical manufacturing operations are limited on the island, and we have arranged deliveries of both gases from the U.S. mainland and other countries. However, it is possible that we may not be able to secure the fuel needed to continuously operate our back-up generators until electrical power is permanently restored or the medical-grade gases needed to continue our operations until a reliable supply chain can be established. Many locations on the island depend upon electricity to power the pumps that deliver clean water. The breakdown of infrastructure and basic services across the island, including communication (telephone, cellular and internet), transportation, utilities and sanitation, may also make it more difficult, time consuming and expensive for us to operate our manufacturing facility and to get supplies and manufactured products transported to and from that location. Even if our facility remains operable and accessible, it may become challenging for some of our local staff to return to work or continue to work. While nearly all of our staff have already returned to work, some of them or their families may now or in the future be without housing, access to food and water, electricity, healthcare, childcare, transportation or other essentials, and for these or other reasons may be forced or elect to temporarily or permanently relocate elsewhere on or off the island. A substantial disruption in our ability to operate our Puerto Rico manufacturing facility (whether due to problems with the facility itself, the infrastructure and services available on the island, the unavailability of raw materials or supplies from vendors, the unavailability of key staff or otherwise) could materially and adversely affect our ability to supply our products and affect our product sales. See our Annual Report on Form 10-K for the year ended December 31, 2016, Part I, Item 1A. Risk Factors— Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

The impact of Hurricane Maria is certain to place greater stress on the island's already challenged economy. Since June 2015, when the Governor of Puerto Rico announced that the government (including certain government entities) was unable to pay its roughly \$72 billion in debt, the government's liquidity position has continued to deteriorate and public reports indicate that the Puerto Rico government is not making certain payments with respect to its obligations. On June 30, 2016, President Obama signed into law the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA) to provide a mechanism for Puerto Rico to restructure its debt, achieve fiscal responsibility and gain access to capital markets. PROMESA established a federal Financial Oversight and Management Board (Oversight Board) to provide fiscal oversight through the development and approval of fiscal plans and budgets for Puerto Rico and to assist in the debt restructuring. The establishment of the Oversight Board initially provided for an automatic stay of creditor actions against the Puerto Rico government until February 15, 2017, and subsequently extended the automatic stay until May 1, 2017, to pursue voluntary negotiations with the Puerto Rico government's creditors. On May 3, 2017, after negotiations with creditors were unsuccessful and the automatic stay expired, the Oversight Board approved and certified the filing in the U.S. District Court for the District of Puerto Rico of a voluntary petition under Title III of PROMESA for the government of Puerto Rico, following thereafter with similar filings for certain Puerto Rico government entities. Title III of PROMESA provides Puerto Rico with a judicial process for restructuring its

debt similar to, but not identical to, Chapter 9 of the U.S. Bankruptcy Code. Given the severe conditions in Puerto Rico after Hurricane Maria hit the island, it is expected that resolution of Puerto Rico's outstanding debt situation through the PROMESA judicial process will be delayed pending recovery efforts. Additionally, on January 29, 2017, the Puerto Rico government enacted the Puerto Rico Fiscal Emergency and Fiscal Responsibility Act, which, among other things, declared a state of financial emergency in Puerto Rico until May 1, 2017, and authorizes the Governor to designate certain services as essential services, and other services as non-essential in order to prioritize the use of available resources to satisfy Puerto Rico's obligations. On July 19, 2017, the Puerto Rico government extended the emergency period through December 31, 2017, and authorized the Governor to further extend the emergency period for six-month terms under certain conditions. While PROMESA and the actions above continue to be important factors in moving Puerto Rico toward economic stability, there is still a risk that Puerto Rico's economic situation prior to Hurricane Maria, as well as the severe impact to the island from the hurricane, could impact the territorial government's provision of utilities or other services in Puerto

Rico that we use in the operation of our business, create the potential for increased taxes or fees to operate in Puerto Rico, result in a migration of workers from Puerto Rico to the mainland United States, and/or make it more expensive or difficult for us to operate in Puerto Rico.

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

We are increasingly dependent on information technology systems, infrastructure, network connected control systems and data security. The breadth, complexity and business process integration of our computer systems and the potential value of our data make these systems targets of service interruption, destruction, malicious intrusion and attack. Likewise, data privacy or security breaches by employees, contractors or others may pose risks that sensitive data, including intellectual property, trade secrets or personal information belonging us, our patients, customers and/or other business partners, may be exposed to unauthorized persons or the public. As a global biotechnology company, our systems, those of our third-party service providers, and those of key business partners with which we interact are subject to frequent cyber-attacks. Moreover, as the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Such attacks could include the deployment of harmful and virulent malware, key loggers, a denial-of-service, delivery of malware through malicious websites, the use of social engineering and/or other means to disrupt business operations or affect the confidentiality, integrity and availability of our information technology systems, processes, infrastructure and data. For example, a number of recent high-profile cyber-attacks against multi-national peer companies, contractors and government agencies have significantly disrupted business operations or resulted in substantial breaches of personal information. Key business partners, third-party service and product providers and any companies we may acquire face similar risks, and any security breaches of their systems could adversely affect our security, expose our confidential data or leave us without access to important systems, products, raw materials, components, services or information. Although in the past we have experienced cyber-attacks and intrusions into our computer systems, we do not believe such attacks have had a material adverse effect on our operations. While we continue to invest in the protection and monitoring of our critical or sensitive data and information technology, there can be no assurance that our efforts will prevent service interruptions or detect all breaches to our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us.

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

During the three months ended September 30, 2017, we had one outstanding stock repurchase program and the repurchase activity was as follows:

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program ⁽¹⁾
July 1 - 31	1,564,921	\$174.82	1,564,921	\$2,241,110,984
August 1 - 31	1,814,178	\$171.12	1,814,178	\$1,930,666,113
September 1 - 30	1,001,177	\$184.83	1,001,177	\$1,745,620,168
	4,380,276	\$175.58	4,380,276	

(1) In October 2017, our Board of Directors authorized an increase that resulted in a total of \$5.0 billion available under the stock repurchase program.

Item 6. EXHIBITS

Reference is made to the Index to Exhibits included herein.

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 25, 2017 By: /S/ DAVID W. MELINE

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

AMGEN INC.

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, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
- 4.6 Officer's Certificate of Amgen Inc., dated January 1, 1992, as supplemented by the First Supplemental Indenture, dated February 26, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
- 4.7 Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
- 4.8 Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
- 4.9 Officers' Certificate of Amgen Inc., dated May 30, 2007, including forms of the Company's Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
- 4.10 Officers' Certificate of Amgen Inc., dated May 23, 2008, including forms of the Company's 6.15% Senior Notes due 2018 and 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)
- 4.11 Officers' Certificate of Amgen Inc., dated January 16, 2009, including forms of the Company's 5.70% Senior Notes due 2019 and 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)
- 4.12

Edgar Filing: AMGEN INC - Form 10-Q

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.)

42

Edgar Filing: AMGEN INC - Form 10-Q

- Exhibit No. Description
- 4.17 Officers' Certificate of Amgen Inc., dated May 15, 2012, including forms of the Company's 2.125% Senior Notes due 2017, 3.625% Senior Notes due 2022 and 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)
- 4.18 Officers' Certificate of Amgen Inc., dated September 13, 2012, including forms of the Company's 2.125% Senior Notes due 2019 and 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)
- 4.19 Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
- 4.20 Officers' Certificate of Amgen Inc., dated May 22, 2014, including forms of the Company's Senior Floating Rate Notes due 2017, Senior Floating Rate Notes due 2019, 1.250% Senior Notes due 2017, 2.200% Senior Notes due 2019 and 3.625% Senior Notes due 2024. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
- 4.21 Officer's Certificate of Amgen Inc., dated May 1, 2015, including forms of the Company's 2.125% Senior Notes due 2020, 2.700% Senior Notes due 2022, 3.125% Senior Notes due 2025 and 4.400% Senior Notes due 2045. (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.)
- 4.22 Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including forms of the Company's 1.250% Senior Notes due 2022 and 2.000% Senior Notes due 2026. (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.)
- 4.23 Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
- 4.24 Terms of the Bonds for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
- 4.25 Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
- 4.26 Registration Rights Agreement, dated as of June 14, 2016, by and among Amgen Inc., Credit Suisse Securities (USA) LLC, J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Mizuho Securities USA Inc., as lead dealer managers, and Drexel Hamilton, LLC and The Williams Capital Group, L.P., as co-dealer managers. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
- 4.27 Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 1.850% Senior Notes due 2021, 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
- 4.28 Officer's Certificate of Amgen Inc., dated as of May 11, 2017, including forms of the Company's Senior Floating Rate Notes due 2019, Senior Floating Rate Notes due 2020, 1.900% Senior Notes due 2019, 2.200% Senior Notes due 2020 and 2.650% Senior Notes due 2022. (Filed as an exhibit to Form 8-K on May 11, 2017 and incorporated herein by reference.)

- 10.1+ Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
- 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 20, 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.)
- 10.5+ Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 20, 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.)

Edgar Filing: AMGEN INC - Form 10-Q

Exhibit No.	Description
10.6+	<u>Amgen Inc. 2009 Performance Award Program. (As Amended on March 2, 2016.)</u> (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)
10.7+	<u>Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on December 20, 2016.)</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.)
10.8+	<u>Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on March 6, 2013.)</u> (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
10.9+	<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 March 6, 2013.)</u> (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
10.11+	<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.)
10.12+	<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.)
10.13+	<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.)
10.14+	<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.)
10.15+	<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.)
10.16+	<u>Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017.</u> (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.17+	<u>Amgen Nonqualified Deferred Compensation 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.)
10.18+	<u>First Amendment to the Amgen Nonqualified Deferred Compensation 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.)

- 10.19+ 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.)
- 10.20+ 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.)
- 10.21+ 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.)
- 10.22 Shareholders' Agreement, dated May 11, 1984, among Amgen, Kirin Brewery Company, Limited and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
- 10.23 Amendment No. 1 dated March 19, 1985, Amendment No. 2 dated July 29, 1985 (effective July 1, 1985), and Amendment No. 3, dated December 19, 1985, to the Shareholders' Agreement dated May 11, 1984. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)

Edgar Filing: AMGEN INC - Form 10-Q

- Exhibit No. Description
- 10.24 Amendment No. 4 dated October 16, 1986 (effective July 1, 1986), Amendment No. 5 dated December 6, 1986 (effective July 1, 1986), Amendment No. 6 dated June 1, 1987, Amendment No. 7 dated July 17, 1987 (effective April 1, 1987), Amendment No. 8 dated May 28, 1993 (effective November 13, 1990), Amendment No. 9 dated December 9, 1994 (effective June 14, 1994), Amendment No. 10 effective March 1, 1996, and Amendment No. 11 effective March 20, 2000 to the Shareholders' Agreement, dated May 11, 1984. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
- 10.25 Amendment No. 12 to the Shareholders' Agreement, dated January 31, 2001. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2005 on August 8, 2005 and incorporated herein by reference.)
- 10.26 Amendment No. 13 to the Shareholders' Agreement, dated June 28, 2007 (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
- 10.27 Amendment No. 14 to the Shareholders' Agreement, dated March 26, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2014 on April 30, 2014 and incorporated herein by reference.)
- 10.28 Assignment and License Agreement, dated October 16, 1986 (effective July 1, 1986), between Amgen and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
- 10.29 G-CSF United States License Agreement, dated June 1, 1987 (effective July 1, 1986), Amendment No. 1, dated October 20, 1988, and Amendment No. 2, dated October 17, 1991 (effective November 13, 1990), between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
- 10.30 G-CSF European License Agreement, dated December 30, 1986, between Kirin-Amgen and Amgen, Amendment No. 1 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated June 1, 1987, Amendment No. 2 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated March 15, 1998, Amendment No. 3 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated October 20, 1988, and Amendment No. 4 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated December 29, 1989, between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
- 10.31 Amended and Restated Credit Agreement, dated July 30, 2014, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent. (Filed as an exhibit to Form 8-K on July 30, 2014 and incorporated herein by reference.)
- 10.32 Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)
- 10.33 Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request

for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)

10.34 Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)

10.35 Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)

10.36 Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)

10.37 Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)

Edgar Filing: AMGEN INC - Form 10-Q

Exhibit No.	Description
10.38	<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.)
10.39	<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.)
10.40	<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.)
10.41	<u>Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG</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 June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.42	<u>Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG</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 June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.43	<u>Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG</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 June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.44	<u>Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG</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 June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
31*	<u>Rule 13a-14(a) Certifications.</u>
32**	<u>Section 1350 Certifications.</u>
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)

46