AMGEN INC
Form 10-Q
October 28, 2016
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q
(Mark One)
þ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016
OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission file number 001-37702
Amgen Inc.
(Exact name of registrant as specified in its charter)

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

(805) 447-1000
(Registrant's telephone number, including area code)
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 þ 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 þ 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" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ¨ No þ
As of October 24, 2016, the registrant had 743,922,473 shares of common stock, $0.0001 par value, outstanding.

AMGEN INC.
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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,		Nine months ended September 30,	
	2016	2015	2016	2015
Revenues:				
Product sales	$5,516	$5,516	$16,229	$15,615
Other revenues	295	207	797	511
Total revenues	5,811	5,723	17,026	16,126
Operating expenses:				
Cost of sales	1,027	1,034	3,095	3,156
Research and development	990	1,119	2,762	2,977
Selling, general and administrative	1,244	1,244	3,739	3,430
Other	23	(13)	121	126
Total operating expenses	3,284	3,384	9,717	9,689
Operating income	2,527	2,339	7,309	6,437
Interest expense, net	325	282	932	811
Interest and other income, net	216	135	503	439
Income before income taxes	2,418	2,192	6,880	6,065
Provision for income taxes	401	329	1,093	926
Net income	$2,017	$1,863	$5,787	$5,139
Earnings per share:				
Basic	$2.70	$2.46	$7.70	$6.76
Diluted	$2.68	$2.44	$7.63	$6.70
Shares used in calculation of earnings per share:				
Basic	747	757	752	760
Diluted	753	764	758	767
Dividends paid per share	$1.00	$0.79	$3.00	$2.37

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Net income	$2,017	$1,863	$5,787	$5,139
Other comprehensive income (loss), net of reclassification adjustments and taxes:				
Foreign currency translation gains (losses)	9	(86)	25	(241)
Effective portion of cash flow hedges	(16)	(53)	(201)	10
Net unrealized (losses) gains on available-for-sale securities	(27)	(35)	515	(3)
Other	1	5	2	5
Other comprehensive (loss) income, net of taxes	(33)	(169)	341	(229)
Comprehensive income	$1,984	$1,694	$6,128	$4,910

See accompanying notes.

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

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,485	$ 4,144
Marketable securities	34,495	27,238
Trade receivables, net	3,186	2,995
Inventories	2,681	2,435
Other current assets	1,997	1,703
Total current assets	45,844	38,515
Property, plant and equipment, net	4,912	4,907
Intangible assets, net	10,690	11,641
Goodwill	14,802	14,787
Other assets	1,902	1,599
Total assets	$ 78,150	$ 71,449
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 825	$ 965
Accrued liabilities	4,920	5,452
Current portion of long-term debt	4,797	2,247
Total current liabilities	10,542	8,664
Long-term debt	30,526	29,182
Long-term deferred tax liability	2,412	2,239
Other noncurrent liabilities	3,897	3,281
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding—744.8 shares in 2016 and 754.0 shares in 2015	30,691	30,649
Retained earnings (accumulated deficit)	221	(2,086)
Accumulated other comprehensive loss	(139)	(480)
Total stockholders' equity	30,773	28,083
Total liabilities and stockholders' equity	$ 78,150	$ 71,449

See accompanying notes.

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

	Nine months ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net income	$5,787	$5,139
Depreciation and amortization	1,546	1,566
Share-based compensation expense	222	242
Deferred income taxes	80	(251)
Other items, net	93	26
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	(192)	(302)
Inventories	(125)	284
Other assets	(335)	192
Accounts payable	(147)	(74)
Accrued income taxes	(140)	478
Other liabilities	465	358
Net cash provided by operating activities	7,254	7,658
Cash flows from investing activities:		
Purchases of property, plant and equipment	(511)	(389)
Proceeds from the sale of property, plant and equipment	15	271
Purchases of marketable securities	(22,682)	(19,792)
Proceeds from sales of marketable securities	14,072	11,784
Proceeds from maturities of marketable securities	1,932	3,179
Other	(262)	(367)
Net cash used in investing activities	(7,436)	(5,314)
Cash flows from financing activities:		
Net proceeds from issuance of debt	6,713	3,464
Repayment of debt	(2,725)	(2,275)
Repurchases of common stock	(1,982)	(1,684)
Dividends paid	(2,251)	(1,800)
Settlement of contingent consideration obligation	—	(225)
Withholding taxes arising from shares withheld for share-based payments	(254)	(394)
Other	22	65
Net cash used in financing activities	(477)	(2,849)
Decrease in cash and cash equivalents	(659)	(505)
Cash and cash equivalents at beginning of period	4,144	3,731
Cash and cash equivalents at end of period	$3,485	$3,226

See accompanying notes.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2016
(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, 2016, and 2015, 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, 2015, 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, 2016, and June 30, 2016.

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 and $7.3 billion as of September 30, 2016, and December 31, 2015, respectively.

Recent accounting pronouncements and reclassifications

During the first quarter of 2016, we adopted a new accounting standard that amends the presentation for debt issuance costs. See Note 9, Financing arrangements.

During the first quarter of 2016, we adopted a new accounting standard that amends certain aspects of the accounting for employee share-based payments. One aspect of the standard requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized as income tax benefits and expenses in the income statement. See Note 4, Income taxes. Previously, such amounts were recognized as increases and decreases in common stock and additional paid-in capital. This aspect of the standard was adopted prospectively, and accordingly, the Provision for income taxes for the three and nine months ended September 30, 2016, includes $7 million and $121 million, respectively, of excess tax benefits arising from share-based payments. The new standard also amends the presentation of employee share-based payment-related items in the statement of cash flows by requiring (i) that excess income tax benefits and deficiencies be classified in cash flows from operating activities (such amounts were previously included in cash flows from financing activities) and (ii) that cash paid to taxing authorities arising from the withholding of shares from employees be classified in cash flows from financing activities (such amounts were previously included in cash flows from operating activities). We adopted the aspects of the standard affecting the cash flow presentation retrospectively, and accordingly, to conform to the current year presentation, in the Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2015, we reclassified: (a) $247 million of excess tax benefits from Net cash used in financing activities to Net cash provided by operating activities and (b) $394 million of cash paid to taxing authorities arising from withholding of shares from employees from Net cash provided by operating activities to Net cash used in financing activities.

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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, and may be adopted earlier, but not before January 1, 2017. The revenue standards are required to be adopted by taking either a full retrospective approach or a modified retrospective approach. We are currently evaluating the impact that the revenue standards will have on our consolidated financial statements and determining the transition method that we will apply.

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

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 and disclose qualitative and quantitative information about their leasing arrangements. The new standard is effective for interim and annual periods beginning on January 1, 2019. We are currently evaluating the impact that this new standard will have on our consolidated financial statements.

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 through an allowance for such losses 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. We are currently evaluating the impact that this new standard will have on our consolidated financial statements.

Certain amounts in the Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2015, have been reclassified from Accounts payable to Other liabilities within Changes in operating assets and liabilities, net of acquisitions to conform to the current year presentation.

2. Restructuring

We continue to execute on the transformation and process improvement efforts announced in 2014. 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 efforts include a restructuring, which is also delivering cost savings and is funding investments. As part of the restructuring, we have exited our 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 consisting primarily of asset impairments, accelerated depreciation and other related costs resulting from the consolidation of our worldwide facilities. Through September 30, 2016, we have incurred $473 million of separation and other headcount-related costs and $225 million of asset-related charges. We expect that we will incur most of the remaining estimated costs through 2017 in order to support our ongoing transformation and process improvement efforts.

The amounts related to the restructuring recorded in the Condensed Consolidated Statements of Income during the three and nine months ended September 30, 2016, were not significant. As of September 30, 2016, the total restructuring liability was not significant.

3. Business combinations

Dezima Pharma B.V.

On October 14, 2015, we acquired all of the outstanding stock of Dezima Pharma B.V. (Dezima), a privately-held, Netherlands-based biotechnology company focused on developing innovative treatments for dyslipidemia. Dezima’s

lead molecule is AMG 899 (formerly TA-8995), an oral, once-daily cholesteryl ester transfer protein inhibitor that has completed certain phase 2 trials. This transaction was accounted for as a business combination. Upon its acquisition, Dezima became a wholly owned subsidiary of Amgen, and its operations have been included in our consolidated financial statements commencing on the acquisition date.

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

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

In connection with this acquisition, we are obligated to make additional payments to the former shareholders of Dezima of up to $1.25 billion contingent upon the achievement of certain development and sales-related milestones. In addition, low-single-digit royalties will be paid on net product sales above a certain threshold. The estimated fair values of the contingent consideration obligations aggregated to $110 million as of the acquisition date. See Note 11, Fair value measurement.

The fair values of assets acquired and liabilities assumed included primarily in-process research and development (IPR&D) of $400 million, goodwill of $108 million and deferred tax liabilities of $100 million. This valuation reflects delayed development pending competitor clinical trials in this class.

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

4. Income taxes

The effective tax rates for the three and nine months ended September 30, 2016, were 16.6% and 15.9%, respectively, compared with 15.0% and 15.3% 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 increase in our effective tax rate for the three months ended September 30, 2016, was due primarily to the unfavorable tax impact of changes in the jurisdictional mix of income and expenses.

The increase in our effective tax rate for the nine months ended September 30, 2016, was due primarily to the unfavorable tax impact of changes in the jurisdictional mix of income and expenses and a state tax audit settlement in the prior year. The increase was offset partially by the adoption of a new accounting standard that amends certain aspects of the accounting for employee share-based compensation payments and discrete benefits associated with tax incentives.

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 4.0% effective through December 31, 2017. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in cost of sales when the related products are sold. For U.S. income tax purposes, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes when the excise tax is incurred.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely audited by the tax authorities in those jurisdictions. Significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws and regulations.

We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009, or to California state income tax examinations for years ended on or before December 31, 2008. We are currently under audit in several jurisdictions, including a U.S. federal income tax examination for tax years ended December 31, 2010, 2011 and 2012. Tax audits can involve complex issues, interpretations and judgments; and their resolution can take many years, particularly if subject to negotiation or litigation. Our assessments of uncertain tax benefits are based on information available to us at this time, including estimates and assumptions that have been deemed appropriate by management but may not be representative of final audit resolutions.

During the three and nine months ended September 30, 2016, the gross amount of our unrecognized tax benefits (UTBs) increased by approximately $115 million and $335 million, respectively, as a result of tax positions taken during the current year. Substantially all of the UTBs as of September 30, 2016, if recognized, would affect our effective tax rate.

5. 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,		Nine months ended September 30,	
	2016	2015	2016	2015
Income (Numerator):				
Net income for basic and diluted EPS	$2,017	$1,863	$5,787	$5,139
Shares (Denominator):				
Weighted-average shares for basic EPS	747	757	752	760
Effect of dilutive securities	6	7	6	7
Weighted-average shares for diluted EPS	753	764	758	767
Basic EPS	$2.70	$2.46	$7.70	$6.76
Diluted EPS	$2.68	$2.44	$7.63	$6.70

For the three and nine months ended September 30, 2016 and 2015, the number of anti-dilutive employee share-based awards excluded from the computation of diluted EPS was not significant.

6. Available-for-sale investments

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

Type of security as of September 30, 2016	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. Treasury securities	$ 7,495	$ 55	$ (3)	$ 7,547
Other government-related debt securities:				
U.S.	302	1	—	303
Foreign and other	1,773	52	(2)	1,823
Corporate debt securities:				
Financial	8,381	110	(2)	8,489
Industrial	8,636	142	(8)	8,770
Other	1,040	15	(1)	1,054
Residential mortgage-backed securities	2,106	8	(5)	2,109
Other mortgage- and asset-backed securities	1,759	7	(4)	1,762
Money market mutual funds	2,089	—	—	2,089
Other short-term interest-bearing securities	3,619	—	—	3,619
Total interest-bearing securities	37,200	390	(25)	37,565
Equity securities	124	39	—	163
Total available-for-sale investments	$ 37,324	$ 429	$ (25)	$ 37,728

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

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, 2016	December 31, 2015
Cash and cash equivalents	$ 3,070	$ 3,738
Marketable securities	34,495	27,238
Other assets — noncurrent	163	136
Total available-for-sale investments	$ 37,728	$ 31,112

Cash and cash equivalents in the above table excludes cash of $415 million and $406 million as of September 30, 2016, and December 31, 2015, respectively.

The fair values of available-for-sale interest-bearing securities 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, 2016	December 31, 2015
Maturing in one year or less	$ 7,121	$ 4,578
Maturing after one year through three years	10,900	9,370
Maturing after three years through five years	12,068	9,932
Maturing after five years through ten years	3,525	3,087
Maturing after ten years	80	70
Mortgage- and asset-backed securities	3,871	3,939
Total interest-bearing securities	$ 37,565	$ 30,976

For the three months ended September 30, 2016 and 2015, realized gains totaled $215 million and $19 million, respectively, and realized losses totaled $192 million and $58 million, respectively. For the nine months ended September 30, 2016 and 2015, realized gains totaled $283 million and $73 million, respectively, and realized losses totaled $313 million and $156 million, respectively. The cost of securities sold is based on the specific identification method.

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

Type of security as of September 30, 2016	Less than 12 months		12 months or greater	
	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	$957	$ (3)	$—	$ —
Other government-related debt securities:				
U.S.	77	—	—	—
Foreign and other	192	(2)	18	—
Corporate debt securities:				
Financial	638	(2)	47	—
Industrial	1,275	(6)	204	(2)
Other	110	(1)	25	—
Residential mortgage-backed securities	667	(2)	182	(3)
Other mortgage- and asset-backed securities	266	(2)	102	(2)
Total	$4,182	$ (18)	$578	$ (7)

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

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 securities 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, 2016, and December 31, 2015, 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, 2016	December 31, 2015
Raw materials	$ 220	$ 201
Work in process	1,356	1,529
Finished goods	1,105	705
Total inventories	$ 2,681	$ 2,435

8. Goodwill and other intangible assets

Goodwill

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

	Nine months ended September 30,	
	2016	2015
Beginning balance	$14,787	$14,788
Goodwill related to acquisitions of businesses[(1)]	2	—
Currency translation adjustments	13	(114)
Ending balance	$14,802	$14,674

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

Identifiable intangible assets

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

	September 30, 2016			December 31, 2015		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
Finite-lived intangible assets:						
Developed product technology rights	$12,320	$ (5,710)	$ 6,610	$12,310	$ (4,996)	$ 7,314
Licensing rights	3,275	(1,225)	2,050	3,275	(998)	2,277
Research and development technology rights	1,142	(696)	446	1,134	(635)	499
Marketing-related rights	1,348	(764)	584	1,186	(650)	536
Total finite-lived intangible assets	18,085	(8,395)	9,690	17,905	(7,279)	10,626
Indefinite-lived intangible assets:						
IPR&D	1,000	—	1,000	1,015	—	1,015
Total identifiable intangible assets	$19,085	$ (8,395)	$ 10,690	$18,920	$ (7,279)	$ 11,641

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. Research and development (R&D) technology rights consist of technology used in R&D with alternative future uses. Marketing-related intangible assets consist primarily of rights related to the sale and distribution of marketed products.

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. As of September 30, 2016, the projects include primarily AMG 899, acquired in the acquisition of Dezima (see Note 3, Business combinations); oprozomib, acquired in the acquisition of Onyx Pharmaceuticals, Inc. (Onyx); and Parsabiv™ (etelcalcetide), acquired in the acquisition of KAI Pharmaceuticals.

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

During the three months ended September 30, 2016 and 2015, we recognized amortization charges associated with our finite-lived intangible assets of $371 million and $340 million, respectively. During the nine months ended September 30, 2016 and 2015, we recognized amortization charges associated with our finite-lived intangible assets of $1.1 billion and $1.0 billion, respectively. The total estimated amortization charges for our finite-lived intangible assets for the remaining three months ending December 31, 2016, and the years ending December 31, 2017, 2018, 2019, 2020 and 2021, are $372 million, $1.3 billion, $1.2 billion, $1.1 billion, $1.0 billion and $0.9 billion, respectively.

9. Financing arrangements

The principal amounts, fixed contractual coupon rates and aggregate carrying value of our long-term borrowings were as follows (in millions):

	September 30, 2016	December 31, 2015
2.30% notes due 2016 (2.30% 2016 Notes)	$ —	$ 750
2.50% notes due 2016 (2.50% 2016 Notes)	1,000	1,000
2.125% notes due 2017 (2.125% 2017 Notes)	1,250	1,250
Floating Rate Notes due 2017	600	600
1.25% notes due 2017 (1.25% 2017 Notes)	850	850
5.85% notes due 2017 (5.85% 2017 Notes)	1,100	1,100
6.15% notes due 2018 (6.15% 2018 Notes)	500	500
Term Loan due 2018 (Term Loan)	—	1,975
4.375% euro-denominated notes due 2018 (4.375% 2018 euro Notes)	616	599
5.70% notes due 2019 (5.70% 2019 Notes)	1,000	1,000
Floating Rate Notes due 2019	250	250
2.20% notes due 2019 (2.20% 2019 Notes)	1,400	1,400
2.125% euro-denominated notes due 2019 (2.125% 2019 euro Notes)	758	733
4.50% notes due 2020 (4.50% 2020 Notes)	300	300
2.125% notes due 2020 (2.125% 2020 Notes)	750	750
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	—
3.875% notes due 2021 (3.875% 2021 Notes)	1,750	1,750
1.25% euro-denominated notes due 2022 (1.25% 2022 euro Notes)	1,404	—
2.70% notes due 2022 (2.70% 2022 Notes)	500	500
3.625% notes due 2022 (3.625% 2022 Notes)	750	750
0.41% Swiss-franc-denominated bonds due 2023 (0.41% 2023 Swiss franc Bonds)	721	—
2.25% notes due 2023 (2.25% 2023 Notes)	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% euro-denominated notes due 2026 (2.00% 2026 euro Notes)	843	—
2.60% notes due 2026 (2.60% 2026 Notes)	1,250	—
5.50% pound-sterling denominated notes due 2026 (5.50% 2026 pound sterling Notes)	616	700
4.00% pound-sterling denominated notes due 2029 (4.00% 2029 pound sterling Notes)	908	1,032
6.375% notes due 2037 (6.375% 2037 Notes)	552	900
6.90% notes due 2038 (6.90% 2038 Notes)	291	500
6.40% notes due 2039 (6.40% 2039 Notes)	466	1,000
5.75% notes due 2040 (5.75% 2040 Notes)	412	700
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	974	2,250
5.65% notes due 2042 (5.65% 2042 Notes)	487	1,250
5.375% notes due 2043 (5.375% 2043 Notes)	261	1,000
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	1,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	—
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	—
Other notes	100	100
Unamortized bond discounts, premiums and issuance costs, net	(942)	(210)
Total carrying value of debt	$ 35,323	$ 31,429
Less current portion	(4,797)	(2,247)

Total noncurrent debt	$ 30,526	$ 29,182

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The principal amounts of notes denominated in foreign currencies in the above table include €550 million of 4.375% 2018 euro Notes, €675 million of 2.125% 2019 euro Notes, €1,250 million of 1.25% 2022 euro Notes, CHF700 million of 0.41% 2023 Swiss franc Bonds, €750 million of 2.00% 2026 euro Notes, £475 million of 5.50% 2026 pound sterling Notes and £700 million of 4.00% 2029 pound sterling Notes.

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.

During the first quarter of 2016, we retrospectively adopted a new accounting standard that amends the presentation of debt issuance costs. Such costs are now presented as a direct deduction from the carrying amount of the debt liability and not as deferred charges presented as assets in our Condensed Consolidated Balance Sheets. As a result of adopting this new accounting standard, our Condensed Consolidated Balance Sheet as of December 31, 2015, was restated to reflect the impact, which reduced both Other current assets and the Current portion of long-term debt by $3 million and both Other assets and Long-term debt by $124 million.

Debt repayments

During the nine months ended September 30, 2016, we repaid the remaining $1.975 billion of principal on our Term Loan and the $750 million aggregate principal amount of the 2.30% 2016 Notes.

Debt issuances

During the nine months ended September 30, 2016, we issued debt securities in the following offerings:

- In August 2016, we issued $3.75 billion principal amount of notes, consisting of the 1.85% 2021 Notes, 2.25% 2023 Notes, 2.60% 2026 Notes and 4.40% 2045 Notes. We received a $79 million premium on the issuance of $1.0 billion of 4.40% 2045 Notes, which represents a further issuance of, and aggregated into a single series with, the 4.40% 2045 Notes issued in May 2015.
- In March 2016, we issued $704 million principal amount of bonds, consisting of the 0.41% 2023 Swiss franc Bonds (CHF700 million principal amount).
- In February 2016, we issued $2.2 billion aggregate principal amount of notes, consisting of the 1.25% 2022 euro Notes (€1.25 billion principal amount) and the 2.00% 2026 euro Notes (€750 million principal amount).

In the event of a change-in-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 (as well as the debt exchange issuances discussed below) at a price equal to 101% of the principal amount of the notes plus accrued and unpaid interest. In addition, all of these debt securities, except for the Swiss franc Bonds, may be redeemed at any time at our option, in whole or in part, at the principal amount of the notes being redeemed plus accrued and unpaid interest and, except as discussed below, a make-whole amount, which is defined by the terms of the notes. The notes may be redeemed without payment of the make-whole amount if redemption occurs during a specified period of time immediately prior to the maturity dates of the notes. Such time periods range from one to six months prior to the maturity date.

Debt exchange

During the second quarter of 2016, we completed a private offering to exchange portions of certain outstanding senior notes due 2037 through 2043 (collectively, the Old Notes), listed below, for new senior notes, consisting of principal amounts of $1.4 billion of 4.563% 2048 Notes and $3.5 billion of 4.663% 2051 Notes (collectively, the New Notes). The following principal amounts of each series of Old Notes were validly tendered and subsequently canceled (in millions):

	Principal Amount Exchanged
6.375% 2037 Notes	$ 348
6.90% 2038 Notes	209
6.40% 2039 Notes	534
5.75% 2040 Notes	288
5.15% 2041 Notes	1,276
5.65% 2042 Notes	763
5.375% 2043 Notes	739

The New Notes bear lower fixed coupon rates while requiring higher principal repayments on extended maturity dates, compared with the Old Notes that were exchanged. There were no other significant changes to the terms between the Old Notes

and the New Notes. The exchange is considered a debt modification, and there were no cash payments to or cash receipts from the note holders as a result of the exchange. Existing deferred financing costs associated with the Old Notes, as well as discounts associated with the New Notes aggregating $801 million, will be accreted over the term of the New Notes and recorded as Interest expense, net. Transaction costs of $24 million incurred for the exchange were expensed immediately in Interest and other income, net.

10. Stockholders' equity

Stock repurchase program

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

	2016		2015	
	Shares*	Dollars	Shares*	Dollars
First quarter	4.7	$ 690	2.9	$ 451
Second quarter	3.9	591	3.3	515
Third quarter	4.4	747	4.6	703
	12.9	$ 2,028	10.8	$ 1,669

* Shares do not foot due to rounding.

As of September 30, 2016, $2.9 billion remained available under our stock repurchase program. In October 2016, our Board of Directors authorized an increase that resulted in a total of $5.0 billion available under the stock repurchase program.

Dividends

In October 2016, the Board of Directors declared a quarterly cash dividend of $1.00 per share of common stock, which will be paid in December 2016.

In July 2016, March 2016 and December 2015, the Board of Directors declared quarterly cash dividends of $1.00 per share of common stock, which were paid in September 2016, June 2016 and March 2016, respectively.

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, 2015	$ (511)	$ 297	$ (260)	$ (6)	$ (480)
Foreign currency translation adjustments	36	—	—	—	36
Unrealized (losses) gains	—	(117)	379	—	262
Reclassification adjustments to income	—	(166)	30	—	(136)
Income taxes	(3)	104	(51)	—	50
Balance as of March 31, 2016	$ (478)	$ 118	$ 98	$ (6)	$ (268)
Foreign currency translation adjustments	(22)	—	—	—	(22)
Unrealized (losses) gains	—	(144)	268	—	124
Reclassification adjustments to income	—	133	23	—	156
Other	—	—	—	1	1
Income taxes	5	5	(107)	—	(97)
Balance as of June 30, 2016	$ (495)	$ 112	$ 282	$ (5)	$ (106)
Foreign currency translation adjustments	11	—	—	—	11
Unrealized gains (losses)	—	35	(19)	—	16
Reclassification adjustments to income	—	(65)	(23)	—	(88)
Other	—	—	—	1	1
Income taxes	(2)	14	15	—	27
Balance as of September 30, 2016	$ (486)	$ 96	$ 255	$ (4)	$ (139)

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, 2016	Three months ended September 30, 2015	Line item affected in the Statements of Income
Cash flow hedges:			
Foreign currency contract gains	$67	$ 86	Product sales
Cross-currency swap contract losses	(1)	(67)	Interest and other income, net
Forward interest rate contract losses	(1)	—	Interest expense, net
	65	19	Total before income tax
	(27)	(7)	Tax expense
	$38	$ 12	Net of taxes
Available-for-sale securities:			
Net realized gains (losses)	$23	$ (39)	Interest and other income, net
	(8)	15	Tax (expense) benefit
	$15	$ (24)	Net of taxes

Components of AOCI	Amounts reclassified out of AOCI Nine months ended September 30, 2016	Nine months ended September 30, 2015	Line item affected in the Statements of Income
Cash flow hedges:			
Foreign currency contract gains	$242	$ 246	Product sales
Cross-currency swap contract losses	(143)	(114)	Interest and other income, net
Forward interest rate contract losses	(1)	(1)	Interest expense, net
	98	131	Total before income tax
	(39)	(47)	Tax expense
	$59	$ 84	Net of taxes
Available-for-sale securities:			
Net realized losses	$(30)	$ (83)	Interest and other income, net
	—	31	Tax benefit
	$(30)	$ (52)	Net of taxes

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 ~~V~~aluations for which all significant inputs are observable, either directly or indirectly, other than level 1 inputs

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

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

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

Fair value measurement as of September 30, 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	$ 7,547	$ —	$ —	$7,547
Other government-related debt securities:				
U.S.	—	303	—	303
Foreign and other	—	1,823	—	1,823
Corporate debt securities:				
Financial	—	8,489	—	8,489
Industrial	—	8,770	—	8,770
Other	—	1,054	—	1,054
Residential mortgage-backed securities	—	2,109	—	2,109
Other mortgage- and asset-backed securities	—	1,762	—	1,762
Money market mutual funds	2,089	—	—	2,089
Other short-term interest-bearing securities	—	3,619	—	3,619
Equity securities	163	—	—	163
Derivatives:				
Foreign currency contracts	—	43	—	43
Cross-currency swap contracts	—	69	—	69
Interest rate swap contracts	—	205	—	205
Total assets	$ 9,799	$ 28,246	$ —	$38,045
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 35	$ —	$35
Cross-currency swap contracts	—	442	—	442
Contingent consideration obligations in connection with business combinations	—	—	176	176
Total liabilities	$ —	$ 477	$ 176	$653

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

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

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

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

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

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

All of our foreign currency forward and option derivatives contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A- or equivalent by S&P 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. These inputs include foreign currency 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. These inputs, where 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. These 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 were observable either directly or indirectly. These 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. These contingent consideration obligations are recorded at their estimated fair values, and we revalue these obligations each reporting period until the related contingencies are resolved. The fair value measurements of these obligations are based on significant unobservable inputs related to product candidates acquired in business combinations and are reviewed quarterly by management in our R&D and commercial sales organizations. These inputs include, as applicable, estimated probabilities and timing of achieving specified regulatory and commercial milestones and estimated annual sales. Significant changes that increase or decrease the probabilities of achieving the related regulatory and commercial events, shorten or lengthen the time required to achieve such events, or increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of these obligations, as applicable. Changes in 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,	
	2016	2015	2016	2015
Beginning balance	$171	$215	$188	$215
Net changes in valuation	5	(18)	(12)	(18)
Ending balance	$176	$197	$176	$197

As a result of our acquisition of Dezima in October 2015, we are obligated to pay its former shareholders up to $1.25 billion of additional consideration contingent upon achieving certain development and sales-related milestones and low single-digit royalties on net product sales above a certain threshold. The estimated fair values of the contingent consideration obligations had an aggregate value of $110 million at acquisition. See Note 3, Business combinations.

As a result of our acquisition of BioVex Group, Inc. (BioVex), in March 2011, we are obligated to pay its former shareholders up to $325 million of additional consideration contingent if certain sales thresholds are achieved within specified periods of time.

We estimate the fair values of the obligations to former shareholders of Dezima and BioVex by using probability-adjusted discounted cash flows, and we review underlying key assumptions on a quarterly basis. There were no significant changes in the fair values of contingent consideration obligations during the three and nine months ended September 30, 2016 and 2015.

During the nine months ended September 30, 2016 and 2015, there were no transfers of assets or liabilities between fair value measurement levels, and there were no material remeasurements to the fair values of assets and liabilities that are not measured at fair value on a recurring basis.

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 estimate the fair value of our long-term debt (Level 2) by taking into consideration indicative prices obtained from a third-party financial institution that utilizes industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; credit spreads; benchmark yields; foreign currency exchange rates, as applicable; and other observable inputs. As of September 30, 2016, and December 31, 2015, the aggregate fair values of our long-term debt were $39.2 billion and $33.1 billion, respectively, and the carrying values were $35.3 billion and $31.4 billion, respectively.

12. Derivative instruments

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

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates associated primarily with our euro-denominated international product sales. Increases and decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are offset partially by corresponding increases and decreases in 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, 2016, and December 31, 2015, we had open foreign currency forward contracts with notional amounts of $3.5 billion and $3.3 billion, respectively, and open foreign currency option contracts with notional amounts of $178 million and $225 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 entered into cross-currency swap contracts. Under the terms of these 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.

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

	Foreign currency		U.S. dollars	
Hedged notes	Notional amount	Interest rate	Notional amount	Interest rate
2.125% 2019 euro Notes	€ 675	2.125%	$864	2.6 %
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 nine months ended September 30, 2016. 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 August 2016. Gains and losses realized on such contracts, which were designated as cash flow hedges, were recognized in AOCI and are being 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,	
Derivatives in cash flow hedging relationships	2016	2015	2016	2015
Foreign currency contracts	$(26)	$53	$(88)	$346
Cross-currency swap contracts	67	(118)	(128)	(199)
Forward interest rate contracts	(6)	—	(10)	—
Total	$35	$(65)	$(226)	$147

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):

		Three months ended September 30,		Nine months ended September 30,	
Derivatives in cash flow hedging relationships	Statements of Income location	2016	2015	2016	2015
Foreign currency contracts	Product sales	$67	$86	$242	$246
Cross-currency swap contracts	Interest and other income, net	(1)	(67)	(143)	(114)
Forward interest rate contracts	Interest expense, net	(1)	—	(1)	(1)
Total		$65	$19	$98	$131

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, 2016 and 2015. As of September 30, 2016, the amounts expected to be reclassified out of AOCI and into earnings during the next 12 months are approximately $39 million of net gains on our foreign currency and cross-currency swap contracts and approximately $2 million of losses on forward interest rate contracts.

Fair value hedges

To achieve a desired mix of fixed and floating interest rates on our long-term debt, we entered into interest rate swap contracts that qualify 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. We had interest rate swap agreements as of September 30, 2016, and December 31, 2015, with aggregate notional amounts of $6.65 billion. The contracts have rates that range from three-month LIBOR plus 0.4% to three-month LIBOR plus 2.0%.

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 the change in fair value during the period as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. For the three and nine months ended September 30, 2016, we included the unrealized gains on hedged debt of $61 million and unrealized losses of $137 million, respectively, in the same line item, Interest expense, net, in the Condensed Consolidated Statements of Income, as the offsetting unrealized losses of $61 million and unrealized gains of $137 million, respectively, on the related interest rate swap agreements. For the three and nine months ended September 30, 2015, we included the unrealized losses on the hedged debt of $134 million and $140 million, respectively, in the same line item, Interest expense, net, in the Condensed Consolidated Statements of Income, as the offsetting unrealized gains of $134 million and $140 million, respectively, on the related interest rate swap agreements.

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. The exposures are hedged on a month-to-month basis. As of September 30, 2016, and December 31, 2015, the total notional amounts of these foreign currency forward contracts were $874 million and $911 million, respectively.

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

		Three months ended		Nine months ended	
		September 30,		September 30,	
Derivatives not designated as hedging instruments	Statements of Income location	2016	2015	2016	2015
Foreign currency contracts	Interest and other income, net	$ 1	$ 9	$ (33)	$ —

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

	Derivative assets		Derivative liabilities	
September 30, 2016	Balance Sheet location	Fair value	Balance Sheet location	Fair value
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other noncurrent assets	$ 43	Accrued liabilities/ Other noncurrent liabilities	$ 34
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	69	Accrued liabilities/ Other noncurrent liabilities	442
Interest rate swap contracts	Other current assets/ Other noncurrent assets	205	Accrued liabilities/ Other noncurrent liabilities	—
Total derivatives designated as hedging instruments		317		476
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	—	Accrued liabilities	1
Total derivatives not designated as hedging instruments		—		1
Total derivatives		$ 317		$ 477

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

Our derivative contracts that were in liability positions as of September 30, 2016, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due to or from a counterparty under these contracts may be offset against other amounts due 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, 2016 and 2015, 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, 2015, 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 be significant in this Note; 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, 2015; and in Note 13, Contingencies and commitments to our condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2016, and June 30, 2016.

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 class actions with thousands of putative class members. These legal proceedings, as well as other matters, involve various aspects of our business and a variety of claims—including but not limited to patent infringement, marketing, pricing and trade practices and securities law—some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing or 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, 2015, or in Note 13, Contingencies and commitments to our condensed

consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2016 and June 30, 2016, 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, 2015, or in Note 13, Contingencies and commitments to our

condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2016 and June 30, 2016, 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:

Sensipar® (cinacalcet) Patent Litigation

Amgen filed 12 separate lawsuits in the United States District Court for the District of Delaware (the Delaware District Court) for infringement of our U.S. Patent No. 9,375,405 (the '405 Patent) against: (1) Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc., (2) MicroLabs Ltd. and Micro Labs USA, Inc., (3) Watson Laboratories, Inc., Actavis, Inc. and Actavis Pharma, Inc., and (4) Cipla Limited and Cipla USA, Inc., on September 22, 2016; (5) Strides Pharma Global PTE Limited and Strides Pharma, Inc., and (6) Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc., on September 29, 2016; (7) Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc., and (8) Ajanta Pharma Limited and Ajanta Pharma USA, Inc., on October 5, 2016; and (9) Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, and Amneal Pharmaceuticals Co. India Private Limited, (10) Apotex Inc. and Apotex Corp., (collectively, Apotex), (11) Hetero USA Inc., Hetero Labs Ltd. and Hetero Labs Ltd. Unit V, and (12) Breckenridge Pharmaceutical, Inc., on October 11, 2016, respectively. The '405 Patent is entitled "Rapid Dissolution Formulation of a Calcium Receptor-Active Compound" and expires in 2026. In each of the 12 lawsuits, Amgen seeks an order of the Delaware District Court making any U.S. Food and Drug Administration (FDA) approval of the defendants' generic versions of Sensipar® effective no earlier than the expiration of the '405 Patent. On October 26, 2016, Cipla Limited and Cipla USA, Inc. responded to the complaint denying infringement and seeking judgment that the '405 Patent is invalid and/or not infringed.

AMJEVITA™ (adalimumab-atto) Patent Litigation

On August 4, 2016, AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively, AbbVie) filed a lawsuit in the Delaware District Court against Amgen Inc. and Amgen Manufacturing, Ltd. (collectively, Amgen), alleging infringement of U.S Patent Nos. 8,663,945; 8,911,964; 8,916,157; 8,961,973; 8,986,693; 9,096,666; 9,220,781; 9,272,041; 9,359,434; and 9,365,645. AbbVie seeks an injunction prohibiting Amgen from commercializing ABP 501 (also known as AMJEVITA™, a biosimilar to AbbVie's HUMIRA® (adalimumab)) prior to the expiration of the patents-in-suit and compelling Amgen to provide AbbVie with at least 180 days-notice of first commercial marketing. On September 13, 2016, Amgen responded to the complaint denying AbbVie's allegations and counterclaimed, seeking judgment that the patents-in-suit are invalid and/or not infringed by Amgen. On September 23, 2016, the FDA approved AMJEVITA™. On October 7, 2016, AbbVie responded to Amgen's counterclaims.

KYPROLIS® (carfilzomib) Patent Litigation

Our subsidiary Onyx Therapeutics, Inc. (Onyx Therapeutics), filed three separate lawsuits in the Delaware District Court against CIPLA Limited and CIPLA USA, Inc., on October 24, 2016; Sagent Pharmaceuticals, Inc., on October 26, 2016; and Breckenridge Pharmaceutical, Inc., on October 27, 2016, for infringing U.S. Patent Nos. 7,232,818; 7,417,042; 7,491,704; 7,737,112; 8,129,346; 8,207,125; 8,207,126; 8,207,127; and 8,207,297. Onyx Therapeutics also filed a lawsuit in the Delaware District Court against MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc., on October 26, 2016, for infringing U.S. Patent No. 7,737,112. These lawsuits are based on abbreviated new drug applications (ANDAs) that seek approval to market generic versions of KYPROLIS® before expiration of the asserted patent or patents. 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 all asserted patents.

Other Biosimilar Patent Litigations

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

Sandoz Pegfilgrastim Litigation

On June 23, 2016, Sandoz Inc. (Sandoz), a Novartis company, responded to Amgen's patent infringement complaint denying infringement and seeking judgment that the patents-in-suit are not infringed and invalid.

Sandoz Filgrastim Litigation

On August 4, 2016, the U.S. District Court for the Northern District of California entered an order construing patent claim terms of our U.S. Patent Nos. 6,162,427 and 8,940,878.

Sandoz Etanercept Litigation

On August 11, 2016, and subject to the terms of a confidential stipulation, the U.S. District Court for the District of New Jersey (the New Jersey District Court) entered a preliminary injunction prohibiting Sandoz from making, using, importing, selling or offering for sale Sandoz's etanercept product. A claim construction hearing is set for February 15, 2017, and trial is scheduled to start on April 17, 2018. On August 30, 2016, the FDA approved Sandoz's Erelzi™ (etanercept-szzs), a biosimilar to Enbrel® (etanercept).

Apotex Pegfilgrastim/Filgrastim Litigation

On September 9, 2016, Apotex petitioned the U.S. Supreme Court for certiorari, seeking review of the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court) holding that the 180-day notice of commercial marketing is mandatory under the BPCIA and can only be given post-FDA licensure of the biosimilar product.

On September 16, 2016, the U.S. District Court for the Southern District of Florida entered final judgment that Apotex's process of manufacturing its filgrastim and pegfilgrastim products do not infringe our U.S. Patent No. 8,952,138, dismissing without prejudice Apotex's remaining invalidity counterclaim for patent invalidity, and making permanent the injunction compelling Apotex to provide 180-day advance notice of first commercial marketing of its filgrastim and pegfilgrastim products if and when the FDA approves these products. On October 3, 2016, Amgen filed an appeal of the final judgment to the Federal Circuit Court.

Hospira Epoetin Alfa Litigation

On August 5, 2016, the Delaware District Court denied the motion filed by Hospira, Inc. (Hospira), a subsidiary of Pfizer, Inc., to dismiss Amgen's complaint which seeks a declaration that Hospira failed to comply with the commercial notice requirement of the BPCIA. On August 19, 2016, Hospira responded to the complaint denying the allegations of the First Amended Complaint and seeking judgment that the patents-in-suit are invalid and not infringed by Hospira. On August 15, 2016, Amgen moved to amend the First Amended Complaint to add additional bases for infringement of our U.S. Patent No. 5,756,349 and to add three additional third-party defendants. On October 3, 2016, the Delaware District Court granted-in-part and denied-in-part Amgen's motion to amend, permitting Amgen to add the additional bases for infringement but not the additional parties to the existing lawsuit. A claim construction hearing was held on September 21, 2016.

On August 5, 2016, the Federal Circuit Court denied Hospira's motion to dismiss Amgen's appeal, which seeks review of the Delaware District Court's order that Hospira need not provide Amgen discovery of certain of its manufacturing processes which information was withheld by Hospira during the BPCIA dispute resolution process.

Onyx Litigation

The Superior Court of the State of California for the County of San Mateo scheduled a November 18, 2016, hearing for final approval of the settlement between the plaintiffs and the former Onyx directors.

Federal Securities Litigation—In re Amgen Inc. Securities Litigation

On October 25, 2016, the U.S. District Court for the Central District of California (the California Central District Court) issued an order approving the final settlement of this securities class action case.

Federal Derivative Litigation

On October 10, 2016, a joint stipulation was filed with the California Central District Court to lift the stay in the stockholder derivative lawsuit of Durgin v. Sharer, et al. and, that same day, Amgen filed a motion to dismiss for lack of standing. A hearing on the pending motions is set for December 12, 2016.

On October 20, 2016, the California Central District Court issued an order dismissing the Rosenblum v. Sharer, et al. case with prejudice.

ERISA Litigation

The California Central District Court scheduled a November 21, 2016, hearing for preliminary approval of the settlement agreed to by the parties in this Employment Retirement Income Security Act (ERISA) class action case.

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, 2015, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2016 and June 30, 2016. 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® (etanercept), Neulasta® (pegfilgrastim), Aranesp® (darbepoetin alfa), Prolia® (denosumab), Sensipar®/Mimpara® (cinacalcet), XGEVA® (denosumab), EPOGEN® (epoetin alfa), and NEUPOGEN® (filgrastim). We market several other products as well, including Vectibix® (panitumumab), Nplate® (romiplostim) and, more recently launched, KYPROLIS® (carfilzomib), Repatha® (evolocumab), BLINCYTO® (blinatumomab), IMLYGIC® (talimogene laherparepvec) and Corlanor® (ivabradine). Our product sales outside the United States consist principally of sales in Europe, and we continue to expand the commercialization and marketing of our products, including in Latin America, the Middle East and Asia.

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, 2016. 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, 2015, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2016 and June 30, 2016.

Products/Pipeline

Bone Health

Prolia®

- In August 2016, we announced that the phase 3 randomized, double-blind, double-dummy, active-controlled study evaluating the safety and efficacy of Prolia® compared with risedronate in patients receiving glucocorticoid treatment met all primary and secondary endpoints at 12 months.

Romosozumab

- In September 2016, we and UCB, our collaboration partner in the development of romosozumab, announced that the FDA accepted for review the Biologics License Application (BLA) for romosozumab for the treatment of osteoporosis in postmenopausal women at increased risk for fracture. The FDA has set a Prescription Drug User Fee Act target action date of July 19, 2017.

XGEVA®

- In October 2016, we announced that a phase 3 study evaluating XGEVA® versus Zometa® (zoledronic acid) in the prevention of skeletal-related events (SRE) in patients with multiple myeloma met its primary endpoint of non-inferiority in delaying the time to first on-study SRE. The secondary endpoints of superiority in delaying time to first SRE and delaying time to first-and-subsequent SRE were not met.

Cardiovascular

Repatha®

- In September 2016, we announced that the phase 3 GLAGOV (GLobal Assessment of Plaque ReGression with a PCSK9 AntibOdy as Measured by IntraVascular Ultrasound) study evaluating the effect of Repatha® on coronary artery disease met its primary and secondary endpoints.

Oncology/Hematology

BLINCYTO®

- In September 2016, we announced that the FDA approved the supplemental BLA for BLINCYTO® to include new data supporting the treatment of pediatric patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia.

KYPROLIS®

- In September 2016, we announced the top-line results of the phase 3 CLARION (Carfilzomib, Melphalan, Prednisone vs Bortezomib, Melphalan, Prednisone in Newly Diagnosed Multiple Myeloma) study, which evaluated an investigational regimen of KYPROLIS®, melphalan and prednisone versus Velcade® (bortezomib), melphalan and prednisone for 54 weeks in patients with newly diagnosed multiple myeloma who were ineligible for hematopoietic stem-cell transplant. The study did not meet the primary endpoint of superiority in progression-free survival.

Nephrology

Parsabiv™ (etelcalcetide)*

- In August 2016, we announced that the FDA issued a Complete Response Letter for the New Drug Application for Parsabiv™ for the treatment of secondary hyperparathyroidism (sHPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.
- In September 2016, we announced that the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) adopted a positive opinion for the Marketing Authorization of Parsabiv™, recommending approval for the treatment of sHPT in adult patients with CKD on hemodialysis.

* FDA provisionally approved trade name

Neuroscience

Erenumab (formerly AMG 334)

- In September 2016, we announced that the phase 3 ARISE (A phase 3, RandomIzed, double-blind, placebo-controlled Study to Evaluate the efficacy and safety of erenumab in migraine prevention) study evaluating the efficacy of erenumab in episodic migraine prevention, met its primary endpoint. Erenumab is being developed in collaboration with Novartis AG (Novartis).

Biosimilars

AMJEVITA™ (adalimumab-atto) (formerly ABP 501)

- In September 2016, we announced that the FDA approved AMJEVITA™ across all eligible indications of the reference product, HUMIRA® (adalimumab), including treatment of psoriatic arthritis, ankylosing spondylitis and moderate-to-severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis (patients four years of age or older), chronic plaque psoriasis, adult Crohn's disease and ulcerative colitis. For discussion of ongoing, related litigation, see Note 13, Contingencies and commitments, to the condensed consolidated financial statements.

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 September 30,			Nine months ended September 30,		
	2016	2015	Change	2016	2015	Change
Product sales:						
U.S.	$4,383	$4,425	(1)%	$12,819	$12,301	4 %
Rest of the world (ROW)	1,133	1,091	4 %	3,410	3,314	3 %
Total product sales	5,516	5,516	— %	16,229	15,615	4 %
Other revenues	295	207	43 %	797	511	56 %
Total revenues	$5,811	$5,723	2 %	$17,026	$16,126	6 %
Operating expenses	$3,284	$3,384	(3)%	$9,717	$9,689	— %
Operating income	$2,527	$2,339	8 %	$7,309	$6,437	14 %
Net income	$2,017	$1,863	8 %	$5,787	$5,139	13 %
Diluted EPS	$2.68	$2.44	10 %	$7.63	$6.70	14 %
Diluted shares	753	764	(1)%	758	767	(1)%

Global product sales for the three months ended September 30, 2016, were flat as strong unit volume growth in Prolia®, Repatha®, KYPROLIS®, Vectibix®, Sensipar® and XGEVA® was offset by declines in product sales of EPOGEN®, NEUPOGEN® and Neulasta®. The increase in global product sales for the nine months ended September 30, 2016, was driven primarily by ENBREL, Prolia®, KYPROLIS®, Sensipar® and XGEVA®, partially offset by declines in EPOGEN®, NEUPOGEN® and Neulasta®.

The increase in other revenues for the three and nine months ended September 30, 2016, was driven primarily by milestone payments received for licensing transactions and higher Ibrance® (palbociclib) royalty income. We receive an 8% royalty on Ibrance® sales.

The decrease in operating expenses for the three months ended September 30, 2016, was driven by savings resulting from our transformation and process improvement efforts. Operating expenses for the nine months ended September 30, 2016, were flat, as increased investments in new product launches were offset by savings resulting from our transformation and process improvement efforts.

The increases in net income and diluted EPS for the three and nine months ended September 30, 2016, were driven by higher revenues and operating margins.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefits or detriments that such movements have on our international product sales are offset partially by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. By hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros, our hedging activities seek to offset both the positive and negative impacts that foreign

currency exchange rate changes may have on our net income. The net impacts

from changes in foreign currency exchange rates were not material for the three and nine months ended September 30, 2016 and 2015.

Results of operations

Product sales

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

	Three months ended September 30,			Nine months ended September 30,		
	2016	2015	Change	2016	2015	Change
ENBREL	$1,452	$1,459	— %	$4,321	$3,923	10 %
Neulasta®	1,200	1,267	(5)%	3,532	3,559	(1)%
Aranesp®	531	493	8 %	1,567	1,452	8 %
Prolia®	379	320	18 %	1,172	932	26 %
Sensipar®/Mimpara®	415	353	18 %	1,171	1,031	14 %
XGEVA®	394	378	4 %	1,153	1,049	10 %
EPOGEN®	335	489	(31)%	966	1,514	(36)%
NEUPOGEN®	183	284	(36)%	592	786	(25)%
Other products	627	473	33 %	1,755	1,369	28 %
Total product sales	$5,516	$5,516	— %	$16,229	$15,615	4 %

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, 2015: (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, 2016 and June 30, 2016, in section Item 1A. Risk Factors.

ENBREL

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

	Three months ended September 30,			Nine months ended September 30,		
	2016	2015	Change	2016	2015	Change
ENBREL — U.S.	$1,388	$1,392	— %	$4,137	$3,724	11 %
ENBREL — Canada	64	67	(4)%	184	199	(8)%
Total ENBREL	$1,452	$1,459	— %	$4,321	$3,923	10 %

ENBREL sales for the three months ended September 30, 2016, were flat, as an increase in the net selling price was offset by a decline in units due to competition and unfavorable changes in wholesaler and, based on prescription data, end-user inventories.

The increase in ENBREL sales for the nine months ended September 30, 2016, was driven primarily by an increase in net selling price, offset partially by a decline in units due to competition.

We expect relatively little benefit from net selling price changes in 2017.

Neulasta®

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

	Three months ended September 30,			Nine months ended September 30,		
	2016	2015	Change	2016	2015	Change
Neulasta® — U.S.	$1,024	$1,056	(3)%	$2,982	$2,931	2 %
Neulasta® — ROW	176	211	(17)%	550	628	(12)%
Total Neulasta®	$1,200	$1,267	(5)%	$3,532	$3,559	(1)%

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The decreases in global Neulasta® sales for the three and nine months ended September 30, 2016, were driven primarily by a decline in unit demand and wholesaler inventory, offset partially by an increase in net selling price in the United States. As of September 30, 2016, utilization of the Neulasta® OnPro™ kit continues to grow.

Our final material U.S. patent for pegfilgrastim (Neulasta®) expired in October 2015. Therefore, we expect to face competition in the United States, which over time may have a material adverse impact on Neulasta® sales. Apotex, Sandoz (a Novartis company) and most recently in October 2016, Coherus BioSciences, Inc., announced that the FDA has accepted their applications for proposed biosimilar versions of Neulasta®. Subsequently, Novartis has indicated that it received a Complete Response Letter from the FDA and expects to submit data from an additional study in 2018. For discussion of ongoing litigation between us and Apotex and Sandoz, see Note 13, Contingencies and commitments, to the condensed consolidated financial statements.

In addition, supplementary protection certificates issued by certain countries, including France, Germany, Italy, Spain, and the United Kingdom, relating to our European patent for pegfilgrastim (Neulasta®) will expire in August 2017. For further information regarding our patents, see our Annual Report on Form 10-K for the year ended December 31, 2015, Part I, Item 1. Business.

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,			Nine months ended September 30,		
	2016	2015	Change	2016	2015	Change
Aranesp® — U.S.	$275	$239	15 %	$796	$651	22 %
Aranesp® — ROW	256	254	1 %	771	801	(4)%
Total Aranesp®	$531	$493	8 %	$1,567	$1,452	8 %

The increase in global Aranesp® sales for the three months ended September 30, 2016, was driven primarily by higher unit demand due to a shift by some U.S. dialysis customers from EPOGEN® to Aranesp®.

The increase in global Aranesp® sales for the nine months ended September 30, 2016, was driven primarily by higher unit demand due to a shift by some U.S. dialysis customers from EPOGEN® to Aranesp®, offset partially by a decrease in net selling price.

Supplementary protection certificates issued by certain countries, including France, Germany, Italy, Spain, and the United Kingdom, relating to our European patent for darbepoetin alfa (Aranesp®) expired in June 2016. For further information regarding our patents, see our Annual Report on Form 10-K for the year ended December 31, 2015, Part I, Item 1. Business.

Prolia®

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

	Three months ended September 30,			Nine months ended September 30,		
	2016	2015	Change	2016	2015	Change
Prolia® — U.S.	$249	$205	21 %	$756	$590	28 %
Prolia® — ROW	130	115	13 %	416	342	22 %
Total Prolia®	$379	$320	18 %	$1,172	$932	26 %

The increases in global Prolia® sales for the three and nine months ended September 30, 2016, were driven primarily by higher unit demand.

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Sensipar®/Mimpara®

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

	Three months ended September 30,			Nine months ended September 30,		
	2016	2015	Change	2016	2015	Change
Sensipar® — U.S.	$329	$268	23 %	$910	$770	18 %
Sensipar®/Mimpara® — ROW	86	85	1 %	261	261	— %
Total Sensipar®/Mimpara®	$415	$353	18 %	$1,171	$1,031	14 %

The increase in global Sensipar®/Mimpara® sales for the three months ended September 30, 2016, was driven primarily by an increase in net selling price and higher unit demand.

The increase in global Sensipar®/Mimpara® sales for the nine months ended September 30, 2016, was driven primarily by an increase in net selling price and higher unit demand, offset partially by unfavorable changes in wholesaler and, based on prescription data, end-user inventories.

XGEVA®

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

	Three months ended September 30,			Nine months ended September 30,		
	2016	2015	Change	2016	2015	Change
XGEVA® — U.S.	$296	$273	8 %	$842	$752	12 %
XGEVA® — ROW	98	105	(7)%	311	297	5 %
Total XGEVA®	$394	$378	4 %	$1,153	$1,049	10 %

The increases in global XGEVA® sales for the three and nine months ended September 30, 2016, were driven primarily by higher unit demand and net selling price.

EPOGEN®

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

	Three months ended September 30,			Nine months ended September 30,		
	2016	2015	Change	2016	2015	Change
EPOGEN® — U.S.	$335	$489	(31)%	$966	$1,514	(36)%

The decrease in EPOGEN® sales for the three months ended September 30, 2016, was driven primarily by a decline in units, resulting from competition, abnormally high purchases by a large end customer in the prior year and a shift by some U.S. dialysis customers to Aranesp.

The decrease in EPOGEN® sales for the nine months ended September 30, 2016, was driven primarily by a decline in units resulting from competition and a shift by some U.S. dialysis customers to Aranesp®.

Sequentially, EPOGEN® sales were relatively flat for the three months ended September 30, 2016, compared with the three months ended June 30, 2016, as the unit decline moderated and was offset by a favorable change in wholesaler inventory.

Our final material U.S. patent for EPOGEN® expired in May 2015. There is competition in the United States, which has had a material adverse impact on EPOGEN® sales. Further, on December 16, 2014, Hospira submitted a BLA to the FDA under the abbreviated pathway for Retacrit,™ a proposed biosimilar to EPOGEN®. For discussion of ongoing litigation between us and Hospira, see Note 13, Contingencies and commitments, to the condensed consolidated

financial statements.

NEUPOGEN®

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

	Three months ended September 30,			Nine months ended September 30,		
	2016	2015	Change	2016	2015	Change
NEUPOGEN® — U.S.	$127	$218	(42)%	$418	$590	(29)%
NEUPOGEN® — ROW	56	66	(15)%	174	196	(11)%
Total NEUPOGEN®	$183	$284	(36)%	$592	$786	(25)%

The decreases in global NEUPOGEN® sales for the three and nine months ended September 30, 2016, were driven primarily by lower unit demand in the United States and a decrease in net selling price due to the impact of short-acting competition.

There is competition in the United States, which has intensified and will continue to have a material adverse impact on sales of NEUPOGEN®. On September 3, 2015, Sandoz announced it had launched Zarxio®, a biosimilar version of NEUPOGEN®, in the United States. On February 17, 2015, Apotex announced that the FDA had accepted its application for filing under the abbreviated pathway for its proposed biosimilar version of NEUPOGEN®. For discussion of ongoing, related litigation, see Note 13, Contingencies and commitments, to the condensed consolidated financial statements.

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,		
	2016	2015	Change	2016	2015	Change
KYPROLIS® — U.S.	$140	$124	13 %	$411	$333	23 %
KYPROLIS® — ROW	43	13	*	98	31	*
Vectibix® — U.S.	64	54	19 %	172	153	12 %
Vectibix® — ROW	100	78	28 %	296	261	13 %
Nplate® — U.S.	92	84	10 %	262	235	11 %
Nplate® — ROW	59	53	11 %	172	153	12 %
BLINCYTO® — U.S.	19	20	(5)%	61	50	22 %
BLINCYTO® — ROW	10	3	*	25	5	*
Repatha® — U.S.	31	2	*	65	2	*
Repatha® — ROW	9	1	*	18	1	*
Other — U.S.	14	1	*	41	6	*
Other — ROW	46	40	15 %	134	139	(4)%
Total other products	$627	$473	33 %	$1,755	$1,369	28 %
Total U.S. — other products	$360	$285	26 %	$1,012	$779	30 %
Total ROW — other products	267	188	42 %	743	590	26 %
Total other products	$627	$473	33 %	$1,755	$1,369	28 %

* Change in excess of 100%

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

Operating expenses

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

	Three months ended September 30,			Nine months ended September 30,		
	2016	2015	Change	2016	2015	Change
Cost of sales	$1,027	$1,034	(1)%	$3,095	$3,156	(2)%
% of product sales	18.6%	18.7%		19.1%	20.2%	
% of total revenues	17.7%	18.1%		18.2%	19.6%	
Research and development	$990	$1,119	(12)%	$2,762	$2,977	(7)%
% of product sales	17.9%	20.3%		17.0%	19.1%	
% of total revenues	17.0%	19.6%		16.2%	18.5%	
Selling, general and administrative	$1,244	$1,244	—%	$3,739	$3,430	9%
% of product sales	22.6%	22.6%		23.0%	22.0%	
% of total revenues	21.4%	21.7%		22.0%	21.3%	
Other	$23	$(13)	*	$121	$126	(4)%

* Change in excess of 100%

Transformation and process improvements

We continue to execute on the transformation and process improvement efforts announced in 2014. 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 efforts include a restructuring, which also is delivering cost savings and is funding investments.

We continue to estimate that the restructuring will result in pre-tax accounting charges in the range of $800 million to $900 million, of which $698 million was incurred through September 30, 2016. The charges that were recorded related to the restructuring during the three and nine months ended September 30, 2016, were not significant. We expect that we will incur most of the remaining estimated costs through 2017 in order to support our ongoing transformation and process improvement efforts.

In 2016, we remain on track to meet or exceed an estimated $400 million in incremental benefits, versus 2015, from our ongoing transformation and process improvement efforts with over three quarters of this savings achieved through September 30, 2016. These savings will enable continued investment in our pipeline and launch activities.

Cost of sales

Cost of sales decreased to 17.7% and 18.2% of total revenues for the three and nine months ended September 30, 2016, respectively. The decreases were driven primarily by manufacturing efficiencies and higher net selling prices, offset partially by product mix.

Excluding the impact of the Puerto Rico excise tax, cost of sales would have been 16.1% and 16.5% of total revenues for the three and nine months ended September 30, 2016, respectively, compared with 16.4% and 17.8% for the corresponding periods of the prior year. See Note 4, Income taxes, to the condensed consolidated financial statements for further discussion of the Puerto Rico excise tax.

Research and development

The decreases in R&D expenses for the three and nine months ended September 30, 2016, were driven by savings resulting from transformation and process improvement efforts, as well as by lower spending required to support certain later-stage clinical programs. The decreases were offset partially by reinvestment for the long-term benefit of the Company, including increases in up-front payments for several in-licensing transactions.

For the three and nine months ended September 30, 2016, costs associated with our later-stage clinical programs support decreased by $200 million and $765 million, respectively, offset by increased costs in marketed products support of $51 million and $538 million, respectively. Discovery Research and Translational Sciences spend was relatively unchanged for both periods. Prior to approval, costs related to our launch products were categorized largely as later-stage clinical programs.

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Selling, general and administrative

Selling, general and administrative (SG&A) expenses for the three months ended September 30, 2016, were flat. The increase in SG&A expenses for the nine months ended September 30, 2016, was driven primarily by investments in new product launches and a $73 million charge related to an acquisition. Both periods benefited from transformation and process improvement efforts.

Other

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, also included legal proceeding charges of $105 million.

Other operating expenses for the three and nine months ended September 30, 2015, included a $32 million gain for the sale of assets related to our site closures and a decrease in the estimated aggregate fair value of a contingent consideration obligation of $18 million, offset partially by a $28 million charge associated with the write-off of a non-key contract asset acquired in a prior year business combination. The nine months ended September 30, 2015, also included certain charges related to our restructuring and other cost savings initiatives, primarily severance of $73 million and a legal proceeding charge of $71 million.

Non-operating expenses/income and income taxes

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Interest expense, net	$325	$282	$932	$811
Interest and other income, net	$216	$135	$503	$439
Provision for income taxes	$401	$329	$1,093	$926
Effective tax rate	16.6 %	15.0 %	15.9 %	15.3 %

Interest expense, net

The increases in Interest expense, net, for the three and nine months ended September 30, 2016, were due primarily to a higher average amount of fixed-rate debt outstanding.

Interest and other income, net

The increases in Interest and other income, net, for the three and nine months ended September 30, 2016, were due primarily to higher interest income that resulted from higher average cash balances and net gains on sales of interest-bearing securities, offset partially by higher gains on sales of strategic equity investments in the prior year.

Income taxes

The increase in our effective tax rate for the three months ended September 30, 2016, was due primarily to the unfavorable tax impact of changes in the jurisdictional mix of income and expenses.

The increase in our effective tax rate for the nine months ended September 30, 2016, was due primarily to the unfavorable tax impact of changes in the jurisdictional mix of income and expenses and a state tax audit settlement in the prior year. The increase was offset partially by the adoption of a new accounting standard that amends certain aspects of the accounting for employee share-based compensation payments and discrete benefits associated with tax incentives.

Excluding the impact of the Puerto Rico excise tax, our effective tax rates for the three and nine months ended September 30, 2016, would have been 19.4% and 18.8%, respectively, compared with 18.4% and 18.7% for the corresponding periods of the prior year.

See Note 4, Income taxes, to the condensed consolidated financial statements for further discussion.

Financial condition, liquidity and capital resources

Selected financial data was as follows (in millions):

	September 30, 2016	December 31, 2015
Cash, cash equivalents and marketable securities	$ 37,980	$ 31,382
Total assets	$ 78,150	$ 71,449
Current portion of long-term debt	$ 4,797	$ 2,247
Long-term debt	$ 30,526	$ 29,182
Stockholders' equity	$ 30,773	$ 28,083

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

In December 2015, March 2016 and July 2016, the Board of Directors declared quarterly cash dividends of $1.00 per share of common stock, which were paid on March 8, June 8 and September 8, 2016, respectively. In October 2016, the Board of Directors declared a quarterly cash dividend of $1.00 per share of common stock, which will be paid on December 8, 2016.

We have also returned capital to stockholders through our stock repurchase program. During the nine months ended September 30, 2016 and 2015, we had stock repurchases of $2.0 billion and $1.7 billion, respectively. As of September 30, 2016, $2.9 billion remained available under the Board of Directors-approved stock repurchase program. In October 2016, our 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. 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, 2015, 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 $38.0 billion as of September 30, 2016, approximately $34.4 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 this arrangement as of September 30, 2016.

Cash flows

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

	Nine months ended September 30,	
	2016	2015
Net cash provided by operating activities	$7,254	$7,658
Net cash used in investing activities	$(7,436)	$(5,314)
Net cash used in financing activities	$(477)	$(2,849)

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, 2016, decreased compared with the same period in the prior year due primarily to the timing of payments to taxing authorities, accelerated inventory production costs and the monetization of foreign currency forward contracts in 2015, offset partially by increased net income.

Investing

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. Cash used in investing activities during the nine months ended September 30, 2015, was due primarily to net activity related to marketable securities of $4.8 billion and capital expenditures of $389 million, offset partially by proceeds from the sale of property, plant and equipment of $271 million. Capital expenditures during the nine months ended September 30, 2016 and 2015, were associated primarily with manufacturing capacity expansions in various locations as well as other site developments. We currently estimate 2016 spending on capital projects and equipment to be approximately $700 million.

Financing

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, repurchases of our common stock of $2.0 billion and withholding taxes arising from shares withheld for share-based payments of $254 million, offset partially by proceeds from the issuance of debt, net of repayments, of $4.0 billion. Cash used in financing activities during the nine months ended September 30, 2015, was due primarily to the payment of dividends of $1.8 billion, repurchases of our common stock of $1.7 billion, withholding taxes arising from shares withheld for share-based payments of $394 million and the settlement of an obligation incurred in connection with the acquisition of Onyx of $225 million, offset partially by proceeds from the issuance of debt, net of repayments, of $1.2 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, of our Annual Report on Form 10-K for the year ended December 31, 2015. There were no material changes to our critical accounting policies during the nine months ended September 30, 2016.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Information about our market risk is disclosed in Part II, Item 7A, of our Annual Report on Form 10-K for the year ended December 31, 2015, and is incorporated herein by reference. Except as discussed below, there have been no material changes during the nine months ended September 30, 2016, to the information provided in Part II, Item 7A, of our Annual Report on Form 10-K for the year ended December 31, 2015.

Interest rate sensitive financial instruments

During the first quarter of 2016, we entered into cross-currency swap contracts to hedge the entire principal amount of the debt denominated in euros and Swiss francs that we issued during this period. As of September 30, 2016, we had

open cross-currency swap contracts with aggregate notional amounts of $5.6 billion that effectively convert interest payments and principal

repayment of certain of our foreign currency denominated debt securities to U.S. dollars and are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates as of September 30, 2016, would result in a reduction in the aggregate fair value of our cross-currency swap contracts of approximately $500 million, but would have no material effect on cash flows or income in the ensuing year.

Foreign currency sensitive financial instruments

As of September 30, 2016, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a carrying value of $5.8 billion and a fair value of $6.5 billion. A hypothetical 20% adverse movement in foreign currency exchange rates relative to exchange rates as of September 30, 2016, would result in an increase in fair value of this debt of approximately $1.3 billion and a reduction in income of approximately $1.2 billion but would have no material effect on the related cash flows in the ensuing year. The analysis for this debt does not consider the offsetting impact that hypothetical changes in foreign currency exchange rates would have on the related cross-currency swap contracts which are in place for the majority of the foreign currency denominated debt.

With regard to our $5.6 billion notional amount of cross-currency swap contracts that are designated as cash flow hedges of certain of our debt denominated in euros, pound sterling and Swiss francs, a hypothetical 20% adverse movement in foreign currency exchange rates relative to exchange rates as of September 30, 2016, would result in a reduction in the fair values of these contracts of approximately $1.3 billion but would have no material effect on the related cash flows in the ensuing year. The impact on income during this period from the above mentioned hypothetical adverse movement in foreign currency exchange rates would be fully offset by the corresponding hypothetical changes in the carrying amounts of the related hedged debt.

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, 2016.

Management determined that, as of September 30, 2016, 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 Reports on Form 10-Q for the periods ended September 30, 2016, June 30, 2016 and March 31, 2016, 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 our consolidated financial statements in Part IV of our Annual Report on Form 10-K for the year ended December 31, 2015.

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 facing our business. We have described in our Annual Report on Form 10-K for the fiscal year ended December 31,

2015, the primary risks related to our business, and we periodically update those risks for material developments. Those risks are not the only ones facing us. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions,

geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Below, we are providing, in supplemental form, the material changes to our risk factors that occurred during the past quarter. Our risk factors disclosed in Part I, Item 1A, of our Annual Report, on Form 10-K for the year ended December 31, 2015, and in Part II, Item 1A. our Quarterly Reports, on Form 10-Q for the periods ended June 30, 2016 and March 31, 2016, provide additional disclosure for these supplemental risks and are incorporated herein by reference.

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

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

A substantial portion of our U.S. business relies on reimbursement from the U.S. federal government healthcare programs and private insurance plans regulated by the U.S. federal government. (See our Annual Report on Form 10-K for the year ended December 31, 2015, Part I, Item 1. Business—Reimbursement.) Changes to U.S. federal reimbursement policy may come through legislative actions such as The Patient Protection and Affordable Care Act. For example, discussions continue about proposals that would allow the U.S. federal government to directly negotiate drug prices with pharmaceutical manufacturers or require manufacturers to pay higher rebates in the Medicare Part D setting. Changes in U.S. federal reimbursement policy may also arise as a result of regulations or demonstration projects implemented by the Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for administering Medicare, Medicaid and the Health Insurance Marketplaces. CMS has substantial power to quickly implement policy changes that can significantly affect how our products are covered and reimbursed. State government actions can also affect how our products are covered and reimbursed or create additional pressure on how our products are priced. For example, a recently enacted Vermont law allows state healthcare regulators to identify certain drugs on which the state spends significant health care dollars and for which list prices rose by a certain percentage (which this year includes ENBREL) and to require the manufacturers to submit justifications of the price increases to the state attorney general. Many other states have discussed and debated and are considering new pricing legislation, including state proposals designed to require biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling, or cap, on pharmaceutical products purchased by state agencies. For example, California voters will consider in the November 2016 election a ballot proposition that would prohibit the state from paying a greater price for drugs than the lowest price paid by the U.S. Department of Veterans Affairs. Passage of this California proposition could lead to the introduction of similar ballot initiatives in other states. Legislative or regulatory changes or other government initiatives that decrease the coverage or reimbursement available for our products, require that we pay increased rebates, limit our ability to offer commercial patient co-pay payment assistance or limit the pricing of pharmaceutical products could have a material adverse effect on our business and results of operations.

Payers, including healthcare insurers, pharmacy benefit managers (PBMs) and others, increasingly seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage. Consolidation in the health insurance industry has resulted in a few large insurers and PBMs exerting greater pressure in pricing and usage negotiations with drug manufacturers. Payers are adopting benefit plan changes that shift a greater portion of prescription costs to patients, and some payers may attempt to limit the use of commercial patient co-pay payment assistance programs. Payers also control costs by imposing restrictions on access to our products, such as requiring prior authorizations or step therapy, and may choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. For example, since the launch of Repatha® in

August 2015, the application of utilization management criteria by some payers, including PBMs, has resulted in denials of coverage for a substantial number of patients for whom Repatha® has been prescribed, slowing Repatha® sales. In the current competitive environment, even if the phase 3 ongoing outcomes study evaluating the ability of Repatha® to prevent cardiovascular events meets its clinical endpoints, the application of restrictive utilization management criteria by some payers may continue until the clinical data is reflected in approved product labeling, or even thereafter. Ultimately, further discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products to U.S. government healthcare programs. Pricing data that we submit impacts the payment rates for providers, rebates we pay, and discounts we are required to provide under Medicare, Medicaid and other government drug programs. Government price reporting regulations are complex and may require a manufacturer to update certain previously submitted data. Our price reporting data calculations are reviewed on a monthly and quarterly basis, and based on such reviews we have on occasion restated

previously reported pricing data to reflect changes in calculation methodology, reasonable assumptions and/or underlying data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data we also may be required to pay additional rebates and provide additional discounts.

Outside the United States, we expect that countries will continue to take aggressive actions to reduce their healthcare expenditures. (See our Annual Report on Form 10-K for the year ended December 31, 2015, Part I, Item 1. Business—Reimbursement.) For example, international reference pricing (IRP) is widely used by a large number of countries to control costs based on an external benchmark of a product's price in other countries. IRP policies can quickly and frequently change and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. Any deterioration in the coverage and reimbursement available for our products or in the timeliness or certainty of payment by payers to physicians and other providers could negatively impact the ability or willingness of healthcare providers to prescribe our products for their patients or otherwise negatively affect the use of our products or the prices we receive for them. Such changes could have a material adverse effect on our product sales, business and results of operations.

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

Before we can sell any products, we must conduct clinical trials to demonstrate that our product candidates are safe and effective for use in humans. The results of those clinical trials are used as the basis to obtain approval from regulatory authorities such as the FDA and EMA. (See our Annual Report on Form 10-K for the year ended December 31, 2015, Part I, Item 1A. Risk Factors—Our current products and products in development cannot be sold without regulatory approval.) We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims. The length of time, number of trial sites and patients required for clinical trials vary substantially and therefore, we may spend several years and incur substantial expense in completing certain clinical trials. In addition, we may have difficulty finding a sufficient number of clinical trial sites and subjects to participate in our clinical trials, particularly if competitors are conducting clinical trials in similar patient populations. Patients may withdraw from clinical trials at any time, and privacy laws and/or other restrictions in certain countries may restrict the ability of clinical trial investigators to conduct further follow-up on such patients, which may adversely affect the interpretation of study results. Delays and complications in planned clinical trials can result in increased development costs, associated delays in regulatory approvals and in product candidates reaching the market and revisions to existing product labels.

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

We rely on independent third-party clinical investigators to recruit subjects and conduct clinical trials on our behalf in accordance with the applicable study protocols and laws and regulations. Further, we rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations. We also may acquire companies that have ongoing clinical trials. These trials may not be conducted to the same standards as ours; however, once an acquisition has been completed we assume responsibility for the conduct of the trial, including any potential risks and liabilities associated with the past and prospective conduct of those trials. If regulatory authorities determine that we or others, including

our licensees or the independent investigators selected by us or by a company we have acquired, have not complied with regulations applicable to the clinical trials, those authorities may refuse or reject some or all of the clinical trial data or take other actions which could negatively impact our ability to obtain or maintain marketing approval of the product or indication. If we were unable to market and sell our products or product candidates, our business and results of operations could be materially and adversely affected.

In addition, some of our clinical trials involve drugs manufactured and marketed by other pharmaceutical companies. These drugs may be administered in a clinical trial in combination with one of our products or product candidates or in a head-to-head study comparing the products' or product candidates' relative efficacy and safety. In the event that any of these vendors or pharmaceutical companies have unforeseen issues that negatively impact the quality of their work or create a shortage of supply, or if we are otherwise unable to obtain an adequate supply of these other drugs, our ability to complete our applicable clinical

trials and/or evaluate clinical results may also be negatively impacted. As a result, this could adversely affect our ability to timely file for, gain or maintain regulatory approvals worldwide.

Clinical trials must be designed based on the current standard of medical care. However in certain diseases, such as cancer, the standard of care is evolving rapidly. In these diseases, the duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on standards of medical care that are no longer the current standards by the time such trials are completed, limiting the utility and application of such trials.

We may not obtain favorable clinical trial results and therefore may not be able to obtain regulatory approval for new product candidates, new indications for existing products or maintenance of our current product labels. Participants in clinical trials of our products and product candidates may also suffer adverse medical events or side effects that could, among other factors, delay or terminate the clinical trial program and/or require additional or longer trials to gain approval.

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

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

During the three months ended September 30, 2016, 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	717,888	$162.08	717,888	$3,518,934,577
August 1 - 31	1,857,289	$172.82	1,857,289	$3,197,956,578
September 1 - 30	1,812,513	$170.93	1,812,513	$2,888,135,072
	4,387,690	$170.28	4,387,690	

(1) In October 2016, 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 28, 2016 By: /S/ DAVID W. MELINE
David W. Meline
Executive Vice President and Chief Financial 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 13, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.6	Officer’s Certificate of Amgen Inc., dated January 1, 1992, as supplemented by the First Supplemental Indenture, dated February 26, 1997, establishing a series of securities entitled “8 1/8% Debentures due April 1, 2097.” (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.7	Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.8	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.9	Officers’ Certificate of Amgen Inc., dated May 30, 2007, including forms of the Company’s Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
4.10	Officers’ Certificate of Amgen Inc., dated May 23, 2008, including forms of the Company’s 6.15% Senior Notes due 2018 and 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)
4.11	Officers’ Certificate of Amgen Inc., dated January 16, 2009, including forms of the Company’s 5.70% Senior Notes due 2019 and 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)
4.12	

	Officers' Certificate of Amgen Inc., dated March 12, 2010, including forms of the Company's 4.50% Senior Notes due 2020 and 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.)
4.13	Officers' Certificate of Amgen Inc., dated September 16, 2010, including forms of the Company's 3.45% Senior Notes due 2020 and 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)
4.14	Officers' Certificate of Amgen Inc., dated June 30, 2011, including forms of the Company's 2.30% Senior Notes due 2016, 4.10% Senior Notes due 2021 and 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)
4.15	Officers' Certificate of Amgen Inc., dated November 10, 2011, including forms of the Company's 1.875% Senior Notes due 2014, 2.50% Senior Notes due 2016, 3.875% Senior Notes due 2021 and 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)
4.16	Officers' Certificate of Amgen Inc., dated December 5, 2011, including forms of the Company's 4.375% Senior Notes due 2018 and 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)

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.)
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 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.)
10.5+	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on 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.)
10.6+	Amgen Inc. 2009 Performance Award Program. (As Amended on 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.)
10.7+	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on 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.)

Exhibit No.	Description
10.8+	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
10.9+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.10+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
10.11+	Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.12+*	First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016.
10.13+	Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.)
10.14+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.15+	First Amendment to the Amgen Inc. Executive Incentive Plan, effective December 13, 2012. (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.)
10.16+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.17+*	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016.
10.18+	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.)
10.19+	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.)
10.20	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.)
10.21	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.)
10.22	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.)
10.23	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.)
10.24	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.)
10.25	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.)
10.26	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.)

Exhibit No.	Description
10.27	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.)
10.28	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.)
10.29	Amended and Restated Promotion Agreement, dated December 16, 2001, by and among Immunex Corporation, American Home Products Corporation and Amgen Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Amendment No. 1 to Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
10.30	Description of Amendment No. 1 to Amended and Restated Promotion Agreement, effective July 8, 2003, among Wyeth, Amgen Inc. and Immunex Corporation (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2003 on March 11, 2004 and incorporated herein by reference.)
10.31	Description of Amendment No. 2 to Amended and Restated Promotion Agreement, effective April 20, 2004, by and among Wyeth, Amgen Inc. and Immunex Corporation. (Filed as an exhibit to Amendment No. 1 to Form S-4 Registration Statement on June 29, 2004 and incorporated herein by reference.)
10.32	Amendment No. 3 to Amended and Restated Promotion Agreement, effective January 1, 2005, by and among Wyeth, Amgen Inc. and Immunex Corporation (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2005 on May 4, 2005 and incorporated herein by reference.)
10.33	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.)
10.34	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.)
10.35	Sourcing and Supply Agreement, dated November 15, 2011, by and between Amgen USA Inc, a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 on February 29, 2012 and incorporated herein by reference.)

10.36	Amendment Number 1 to Sourcing and Supply Agreement, effective January 1, 2013, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Healthcare Partners Inc. f/k/a DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.)
10.37	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.)
10.38	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.)
10.39	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.)

Exhibit No.	Description
10.40	Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.41	Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.42	Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

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