AMGEN INC
Form 10-Q
November 02, 2015
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, 2015
OR

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

Commission file number 000-12477
Amgen Inc.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	95-3540776 (I.R.S. Employer Identification No.)
One Amgen Center Drive, Thousand Oaks, California (Address of principal executive offices)	91320-1799 (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 27, 2015, the registrant had 754,327,866 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,	
	2015	2014	2015	2014
Revenues:				
Product sales	$5,516	$4,848	$15,615	$14,153
Other revenues	207	183	511	579
Total revenues	5,723	5,031	16,126	14,732
Operating expenses:				
Cost of sales	1,034	1,068	3,156	3,239
Research and development	1,119	1,018	2,977	3,063
Selling, general and administrative	1,244	1,213	3,430	3,372
Other	(13)	266	126	326
Total operating expenses	3,384	3,565	9,689	10,000
Operating income	2,339	1,466	6,437	4,732
Interest expense, net	282	269	811	810
Interest and other income, net	135	140	439	377
Income before income taxes	2,192	1,337	6,065	4,299
Provision for income taxes	329	93	926	435
Net income	$1,863	$1,244	$5,139	$3,864
Earnings per share:				
Basic	$2.46	$1.63	$6.76	$5.10
Diluted	$2.44	$1.61	$6.70	$5.02
Shares used in calculation of earnings per share:				
Basic	757	761	760	758
Diluted	764	771	767	769
Dividends paid per share	$0.79	$0.61	$2.37	$1.83

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Net income	$1,863	$1,244	$5,139	$3,864
Other comprehensive (loss) income, net of reclassification adjustments and taxes:				
Foreign currency translation losses	(86)	(124)	(241)	(125)
Effective portion of cash flow hedges	(53)	228	10	205
Net unrealized losses on available-for-sale securities	(35)	(94)	(3)	(33)
Other	5	9	5	10
Other comprehensive (loss) income, net of tax	(169)	19	(229)	57
Comprehensive income	$1,694	$1,263	$4,910	$3,921

See accompanying notes.

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

	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$3,226	$3,731
Marketable securities	27,894	23,295
Trade receivables, net	2,901	2,546
Inventories	2,531	2,647
Other current assets	2,292	2,494
Total current assets	38,844	34,713
Property, plant and equipment, net	4,988	5,223
Intangible assets, net	11,613	12,693
Goodwill	14,674	14,788
Other assets	1,750	1,592
Total assets	$71,869	$69,009
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,067	$1,212
Accrued liabilities	4,848	5,296
Current portion of long-term debt	1,250	500
Total current liabilities	7,165	7,008
Long-term debt	30,511	30,215
Long-term deferred tax liability	3,109	3,461
Other noncurrent liabilities	3,117	2,547
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding - 754.9 shares in 2015 and 760.4 shares in 2014	30,556	30,410
Accumulated deficit	(2,352)	(4,624)
Accumulated other comprehensive loss	(237)	(8)
Total stockholders' equity	27,967	25,778
Total liabilities and stockholders' equity	$71,869	$69,009

See accompanying notes.

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

	Nine months ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net income	$5,139	$3,864
Depreciation and amortization	1,566	1,567
Stock-based compensation expense	242	302
Deferred income taxes	(251)	296
Other items, net	(221)	(260)
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	(302)	345
Inventories	284	99
Other assets	192	(120)
Accounts payable	(127)	104
Accrued income taxes	478	(324)
Other liabilities	17	237
Net cash provided by operating activities	7,017	6,110
Cash flows from investing activities:		
Purchases of property, plant and equipment	(389)	(515)
Proceeds from sale of property, plant and equipment	271	—
Cash paid for acquisitions, net of cash acquired	—	(115)
Purchase of intangible assets	(55)	(150)
Purchases of marketable securities	(19,792)	(20,831)
Proceeds from sales of marketable securities	11,784	11,060
Proceeds from maturities of marketable securities	3,179	3,962
Change in restricted investments	—	533
Other	(312)	(70)
Net cash used in investing activities	(5,314)	(6,126)
Cash flows from financing activities:		
Net proceeds from issuance of debt	3,464	4,476
Repayment of debt	(2,275)	(3,480)
Repurchases of common stock	(1,684)	—
Dividends paid	(1,800)	(1,387)
Net proceeds from issuance of common stock in connection with the Company's equity award programs	65	153
Settlement of contingent consideration obligation	(225)	—
Other	247	126
Net cash used in financing activities	(2,208)	(112)
Decrease in cash and cash equivalents	(505)	(128)
Cash and cash equivalents at beginning of period	3,731	3,805
Cash and cash equivalents at end of period	$3,226	$3,677

See accompanying notes.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2015
(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, 2015 and 2014, 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, 2014, 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, 2015, and June 30, 2015.

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 accounting principles generally accepted in the United States (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 $7.4 billion and $7.0 billion as of September 30, 2015, and December 31, 2014, respectively.

Recent accounting pronouncements

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

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

2. Restructuring

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

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We continue to estimate that we will incur $935 million to $1,035 million of pre-tax charges in connection with our restructuring plan, including: (i) separation and other headcount-related costs of $535 million to $585 million with respect to staff reductions, and (ii) asset-related charges of $400 million to $450 million consisting primarily of asset impairments, accelerated depreciation and other related costs resulting from the consolidation of our worldwide facilities. We incurred a total of $482 million of separation and other headcount-related costs and $242 million of asset-related charges through September 30, 2015.

During the three and nine months ended September 30, 2015, we incurred $11 million and $166 million, respectively, of restructuring costs. We expect that we will incur most of the remaining estimated costs, as discussed above, during the remainder of 2015 and in 2016 in order to support our ongoing transformation and process improvement efforts.

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

	Three months ended September 30, 2015				
	Separation costs	Asset impairments	Accelerated depreciation	Other	Total
Cost of sales	$—	$ —	$ 12	$1	$13
Research and development	—	—	6	7	13
Selling, general and administrative	—	—	4	7	11
Other	2	(31)	—	3	(26)
Total	$2	$ (31)	$ 22	$18	$11

	Nine months ended September 30, 2015				
	Separation costs	Asset impairments	Accelerated depreciation	Other	Total
Cost of sales	$—	$ —	$ 38	$4	$42
Research and development	—	—	27	21	48
Selling, general and administrative	—	—	10	25	35
Other	57	(31)	—	15	41
Total	$57	$ (31)	$ 75	$65	$166

We recognized asset impairment and accelerated depreciation charges in connection with our decision to exit Boulder and Longmont, Colorado, Bothell and Seattle, Washington and the consolidation of facilities in Thousand Oaks, California. The decision to close these manufacturing and research and development (R&D) facilities was based principally on optimizing the utilization of our sites in the United States, which includes an expansion of our presence in the key U.S. biotechnology hubs of South San Francisco, California and Cambridge, Massachusetts. During the three months ended September 30, 2015, we recognized a gain from the sale of assets related to these site closures.

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

	During the nine months ended September 30, 2015		
	Separation costs	Other	Total
Restructuring liabilities as of December 31, 2014	$221	$23	$244
Expense	59	56	115
Payments	(172)	(67)	(239)
Restructuring liabilities as of September 30, 2015	$108	$12	$120

3. Income taxes

The effective tax rates for the three and nine months ended September 30, 2015, were 15.0% and 15.3%, respectively, compared with 7.0% and 10.1% for the corresponding periods of the prior year. The effective rates are different from the federal statutory rates primarily as a result of indefinitely reinvested 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 of the United States. In addition, the effective tax rates for the three and nine months ended September 30, 2015 and 2014, were reduced by foreign tax credits associated with the Puerto Rico excise tax described below.

The increase in our effective tax rate for the three months ended September 30, 2015, was due primarily to the unfavorable tax impact of changes in the jurisdictional mix of income and expenses and lower domestic restructuring costs, offset partially by certain discrete items, including a transfer pricing adjustment recognized in the three months ended September 30, 2015.

The increase in our effective tax rate for the nine months ended September 30, 2015, was due primarily to the unfavorable tax impact of changes in the jurisdictional mix of income and expenses and lower domestic restructuring costs, offset partially by certain discrete items, including a state tax audit settlement in the three months ended March 31, 2015, and a transfer pricing adjustment recognized in the three months ended September 30, 2015.

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

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 income and deductions, the use of tax credits and the allocations of income among various tax jurisdictions because of differing interpretations of tax laws and regulations. We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009, or to California state income tax examinations for years ended on or before December 31, 2008.

During the three and nine months ended September 30, 2015, the gross amount of our unrecognized tax benefits (UTBs) increased by approximately $125 million and $335 million, respectively, as a result of tax positions taken during the current year. The UTB balance decreased by approximately $70 million during the nine months ended September 30, 2015, due to state tax audit settlements. Substantially all of the UTBs as of September 30, 2015, if recognized, would affect our effective tax rate.

4. Earnings per share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which include principally shares that may be issued under our stock option awards and restricted stock and performance unit awards, 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,	
	2015	2014	2015	2014
Income (Numerator):				
Net income for basic and diluted EPS	$1,863	$1,244	$5,139	$3,864
Shares (Denominator):				
Weighted-average shares for basic EPS	757	761	760	758
Effect of dilutive securities	7	10	7	11
Weighted-average shares for diluted EPS	764	771	767	769

Basic EPS	$2.46	$1.63	$6.76	$5.10
Diluted EPS	$2.44	$1.61	$6.70	$5.02

For the three and nine months ended September 30, 2015 and 2014, the number of anti-dilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

5. Collaborative arrangements

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

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for non-refundable upfront license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration agreements are performed with no guarantee of either technological or commercial success and each is unique in nature. Below are our significant arrangements which have had material changes in their terms since the filing of our Annual Report on Form 10-K for the year ended December 31, 2014.

AstraZeneca Plc.

We are in a collaboration with AstraZeneca Plc. (AstraZeneca) to jointly develop and commercialize certain antibodies from Amgen's clinical inflammation portfolio, including AMG 157, AMG 181, AMG 557 and AMG 570. The agreement covers the worldwide development and commercialization of these antibodies, except for AMG 557 and AMG 570 in Japan. AMG 139 and brodalumab were formerly part of the collaboration in certain territories. As of April 1, 2015, we suspended our participation in the co-development and commercialization of AMG 139, with the option of resuming such participation at a later date. As of August 26, 2015, we terminated our participation in the co-development and commercialization of brodalumab based on events of suicidal ideation and behavior in the program. From and after such termination, the clinical development and commercialization of brodalumab are at the sole discretion and expense of AstraZeneca. If AstraZeneca commercializes brodalumab, Amgen would receive a mid-single-digit to low-double-digit royalty on net sales of brodalumab.

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

During the three months ended September 30, 2015 and 2014, cost recoveries recognized for development costs, which included brodalumab and AMG 139, were $25 million and $28 million, respectively, which were included in Research and development expense in the Condensed Consolidated Statements of Income. During the nine months ended September 30, 2015 and 2014, the cost recoveries were $48 million and $77 million, respectively.

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

Bayer HealthCare Pharmaceuticals Inc.

As part of the Onyx Pharmaceuticals Inc. (Onyx) transaction, we acquired a collaboration with Bayer HealthCare Pharmaceuticals Inc. (Bayer) to jointly develop and commercialize Nexavar® (sorafenib) worldwide, except in Japan. The rights to develop and market Nexavar® in Japan are reserved to Bayer. Bayer has no obligation to pay royalties to Amgen for sales of Nexavar® in Japan.

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

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

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

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

We do not expect that the amendment to the collaboration will have a material impact on our consolidated results of operations. Prior to the amendment, Amgen was acting as an agent under the agreement and as such, revenue was derived by calculating net sales of Nexavar® to third-party customers and deducting the cost of goods sold, distribution costs, marketing costs, phase 4 clinical trial costs, allocable overhead costs and certain other costs. During the three months ended September 30, 2015 and 2014, Amgen recorded Nexavar® net profits of $48 million and $73 million, respectively, which were recognized as Other revenues in the Condensed Consolidated Statements of Income. During the nine months ended September 30, 2015 and 2014, net profits were $204 million and $238 million, respectively. Pursuant to the May 2015 amendment to the agreement, Amgen recorded royalty income of $33 million on U.S. sales of Nexavar® in Other revenues in the Condensed Consolidated Statements of Income during the three months ended September 30, 2015. In addition, during the three months ended September 30, 2015 and 2014, net R&D expenses related to the agreement were $4 million and $9 million, respectively, which were recognized in the Condensed Consolidated Statements of Income. During the nine months ended September 30, 2015 and 2014, the net R&D expenses were $16 million and $30 million, respectively.

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, 2015	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. Treasury securities	$4,255	$37	$(1)	$4,291
Other government-related debt securities:				
U.S.	704	3	—	707
Foreign and other	1,706	15	(32)	1,689
Corporate debt securities:				
Financial	8,106	33	(19)	8,120
Industrial	8,134	30	(110)	8,054
Other	883	3	(9)	877
Residential mortgage-backed securities	1,514	9	(7)	1,516
Other mortgage- and asset-backed securities	2,251	5	(39)	2,217
Money market mutual funds	2,661	—	—	2,661
Other short-term interest-bearing securities	533	—	—	533
Total interest-bearing securities	30,747	135	(217)	30,665
Equity securities	87	48	—	135
Total available-for-sale investments	$30,834	$183	$(217)	$30,800

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

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

Classification in the Condensed Consolidated Balance Sheets	September 30, 2015	December 31, 2014
Cash and cash equivalents	$2,771	$3,293
Marketable securities	27,894	23,295
Other assets — noncurrent	135	144
Total available-for-sale investments	$30,800	$26,732

Cash and cash equivalents in the table above excludes cash of $455 million and $438 million as of September 30, 2015, and December 31, 2014, respectively.

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

Contractual maturity	September 30, 2015	December 31, 2014
Maturing in one year or less	$3,859	$4,936
Maturing after one year through three years	9,331	6,829
Maturing after three years through five years	10,093	7,840
Maturing after five years through ten years	3,433	3,267
Maturing after ten years	216	218
Mortgage- and asset-backed securities	3,733	3,498
Total interest-bearing securities	$30,665	$26,588

For the three months ended September 30, 2015 and 2014, realized gains totaled $19 million and $17 million, respectively, and realized losses totaled $58 million and $28 million, respectively. For the nine months ended September 30, 2015 and 2014, realized gains totaled $73 million and $102 million, respectively, and realized losses totaled $156 million and $71 million, respectively. The cost of securities sold is based on the specific identification method.

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

	Less than 12 months		12 months or greater	
Type of security as of September 30, 2015	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	$345	$(1)	$18	$—
Other government-related debt securities:				
Foreign and other	931	(29)	61	(3)
Corporate debt securities:				
Financial	2,603	(17)	276	(2)
Industrial	3,957	(85)	745	(25)
Other	480	(7)	33	(2)
Residential mortgage-backed securities	286	(2)	328	(5)
Other mortgage- and asset-backed securities	539	(8)	561	(31)
Total	$9,141	$(149)	$2,022	$(68)

	Less than 12 months		12 months or greater	
Type of security as of December 31, 2014	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	$1,770	$(7)	$171	$(1)
Other government-related debt securities:				
U.S.	160	—	178	(3)
Foreign and other	514	(14)	159	(10)
Corporate debt securities:				
Financial	3,150	(14)	158	(2)
Industrial	3,931	(62)	222	(4)
Other	354	(4)	5	—
Residential mortgage-backed securities	614	(4)	413	(6)
Other mortgage- and asset-backed securities	1,071	(8)	561	(33)
Equity securities	5	(2)	—	—
Total	$11,569	$(115)	$1,867	$(59)

The primary objective of our investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings and 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. This evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below our cost basis and adverse conditions related specifically to the security, including any changes to the credit rating of the security, and the intent to sell, or whether we will more likely than not be required to sell, the security before recovery of its amortized cost basis. Our assessment of whether a security is other-than-temporarily impaired could change in the future due to new developments or changes in assumptions related to any particular security. As of September 30, 2015, and December 31, 2014, 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, 2015	December 31, 2014
Raw materials	$221	$198
Work in process	1,348	1,551
Finished goods	962	898
Total inventories	$2,531	$2,647

8. Goodwill and other intangible assets

Goodwill

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

	Nine months ended September 30,	
	2015	2014
Beginning balance	$14,788	$14,968
Goodwill related to acquisitions of businesses[(1)]	—	(114)
Currency translation adjustments	(114)	(39)
Ending balance	$14,674	$14,815

(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, 2015			December 31, 2014		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
Finite-lived intangible assets:						
Developed product technology rights	$10,808	$(4,779)	$6,029	$10,826	$(4,155)	$6,671
Licensing rights	3,261	(923)	2,338	3,236	(696)	2,540
R&D technology rights	1,153	(640)	513	1,167	(569)	598
Marketing-related rights	1,203	(611)	592	1,241	(512)	729
Total finite-lived intangible assets	16,425	(6,953)	9,472	16,470	(5,932)	10,538
Indefinite-lived intangible assets:						
In-process research and development	2,141	—	2,141	2,155	—	2,155
Total identifiable intangible assets	$18,566	$(6,953)	$11,613	$18,625	$(5,932)	$12,693

Developed product technology rights consist of rights related to marketed products acquired in business combinations. Licensing rights consist primarily of contractual rights acquired 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. 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.

In-process research and development (IPR&D) consists of R&D projects acquired in a business combination which are not complete due to remaining technological risks and/or lack of receipt of the required regulatory approvals. As of September 30, 2015, these projects include Kyprolis® (carfilzomib) for Injection and oprozomib acquired in the acquisition of Onyx, etelcalcetide (formerly AMG 416) acquired in the acquisition of KAI Pharmaceuticals and IMLYGIC™ (talimogene laherparepvec) acquired

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in the acquisition of BioVex Group, Inc. (BioVex). In October 2015, the U.S. Food and Drug Administration (FDA) approved IMLYGIC™ for the local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients with melanoma recurrent after initial surgery. As a result, the $675 million carrying value of IMLYGIC™ will be reclassified from IPR&D to Developed product technology rights during the fourth quarter of 2015, and will be amortized over its estimated useful life.

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

During the three months ended September 30, 2015 and 2014, we recognized amortization charges associated with our finite-lived intangible assets of $340 million and $339 million, respectively. During each of the nine months ended September 30, 2015 and 2014, we recognized amortization charges associated with our finite-lived intangible assets of $1.0 billion. The total estimated amortization charges for our finite-lived intangible assets for the three months ending December 31, 2015, and the years ending December 31, 2016, 2017, 2018, 2019 and 2020, are $348 million, $1.4 billion, $1.2 billion, $1.1 billion, $1.0 billion and $0.9 billion, respectively.

9. Financing arrangements

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

	September 30, 2015	December 31, 2014
2.30% notes due 2016 (2.30% 2016 Notes)	$750	$749
2.50% notes due 2016 (2.50% 2016 Notes)	1,000	1,000
Floating Rate Notes due 2017	600	600
1.25% notes due 2017 (1.25% 2017 Notes)	849	849
2.125% notes due 2017 (2.125% 2017 Notes)	1,249	1,249
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	2,100	4,375
4.375% euro-denominated notes due 2018 (4.375% 2018 euro Notes)	613	668
Floating Rate Notes due 2019	250	250
2.20% notes due 2019 (2.20% 2019 Notes)	1,398	1,398
5.70% notes due 2019 (5.70% 2019 Notes)	999	999
2.125% euro-denominated notes due 2019 (2.125% 2019 euro Notes)	752	814
4.50% notes due 2020 (4.50% 2020 Notes)	300	300
2.125% notes due 2020 (2.125% 2020 Notes)	749	—
3.45% notes due 2020 (3.45% 2020 Notes)	898	898
4.10% notes due 2021 (4.10% 2021 Notes)	998	998
3.875% notes due 2021 (3.875% 2021 Notes)	1,747	1,747
2.70% notes due 2022 (2.70% 2022 Notes)	499	—
3.625% notes due 2022 (3.625% 2022 Notes)	748	747
3.625% notes due 2024 (3.625% 2024 Notes)	1,398	1,398
3.125% notes due 2025 (3.125% 2025 Notes)	995	—
5.50% pound-sterling-denominated notes due 2026 (5.50% 2026 pound sterling Notes)	714	735
4.00% pound-sterling-denominated notes due 2029 (4.00% 2029 pound sterling Notes)	1,046	1,076
6.375% notes due 2037 (6.375% 2037 Notes)	899	899
6.90% notes due 2038 (6.90% 2038 Notes)	499	499
6.40% notes due 2039 (6.40% 2039 Notes)	996	996
5.75% notes due 2040 (5.75% 2040 Notes)	697	697
4.95% notes due 2041 (4.95% 2041 Notes)	596	596
5.15% notes due 2041 (5.15% 2041 Notes)	2,234	2,233
5.65% notes due 2042 (5.65% 2042 Notes)	1,245	1,245
5.375% notes due 2043 (5.375% 2043 Notes)	1,000	1,000
4.40% notes due 2045 (4.40% 2045 Notes)	1,243	—
Other notes	100	100
Total debt	31,761	30,715
Less current portion	(1,250)	(500)
Total noncurrent debt	$30,511	$30,215

Debt repayments

During the nine months ended September 30, 2015, we repaid $2.275 billion of principal on our Term Loan Credit Facility (Term Loan).

Debt issuances

In May 2015, we issued $3.5 billion aggregate principal amount of notes, consisting of the 2.125% 2020 Notes, the 2.70% 2022 Notes, the 3.125% 2025 Notes and the 4.40% 2045 Notes. The notes may be redeemed at any time at our option, in whole or in part, at the principal amount of the notes being redeemed plus accrued and unpaid interest and, except as discussed below, a make-whole amount, as defined. The 2.125% 2020 Notes, the 2.70% 2022 Notes, the 3.125% 2025 Notes and the 4.40% 2045 Notes may be redeemed without payment of a make-whole amount if they are redeemed on or after one, two, three or six months, respectively, prior to their maturity dates. In the event of a change in control triggering event, as defined, we may be required to purchase all or a portion of the notes at a price equal to 101% of the principal amount of the notes plus accrued and unpaid interest. Debt issuance costs incurred in connection with the issuance of these notes totaling approximately $21 million are being amortized over the respective lives of the notes, and the related charge is included in Interest expense, net in the Condensed Consolidated Statements of Income.

10. Stockholders' equity

Stock repurchase program

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

	2015		2014	
	Shares	Dollars	Shares	Dollars
First quarter	2.9	$451	—	$—
Second quarter	3.3	515	—	—
Third quarter	4.6	703	—	—
Total stock repurchases	10.8	$1,669	—	$—

As of September 30, 2015, $2.2 billion remained available under our stock repurchase program. In October 2015, our Board of Directors authorized an increase that resulted in a total of $5.0 billion available under the stock repurchase program.

Dividends

On December 17, 2014, March 4, 2015 and July 28, 2015, the Board of Directors declared quarterly cash dividends of $0.79 per share of common stock, which were paid on March 6, June 5, and September 8, 2015, respectively. On October 14, 2015, the Board of Directors declared a cash dividend of $0.79 per share of common stock, which will be paid on December 7, 2015, to all stockholders of record as of the close of business on November 16, 2015.

Accumulated other comprehensive income

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

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2014	$(264)	$290	$ (19)	$(15)	$(8)
Foreign currency translation adjustments	(184)	—	—	—	(184)
Unrealized gains	—	168	188	—	356
Reclassification adjustments to income	—	114	35	—	149
Income taxes	11	(104)	(83)	—	(176)
Balance as of March 31, 2015	$(437)	$468	$ 121	$(15)	$137
Foreign currency translation adjustments	24	—	—	—	24
Unrealized gains (losses)	—	44	(180)	—	(136)
Reclassification adjustments to income	—	(226)	9	—	(217)
Income taxes	(6)	67	63	—	124
Balance as of June 30, 2015	$(419)	$353	$ 13	$(15)	$(68)
Foreign currency translation adjustments	(88)	—	—	—	(88)
Unrealized (losses) gains	—	(65)	(94)	5	(154)
Reclassification adjustments to income	—	(19)	39	—	20
Income taxes	2	31	20	—	53
Balance as of September 30, 2015	$(505)	$300	$ (22)	$(10)	$(237)

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

Components of AOCI	Amounts reclassified out of AOCI Three months ended September 30, 2015	Three months ended September 30, 2014	Line item affected in the Statements of Income
Cash flow hedges:			
Foreign currency contract gains	$86	$5	Product sales
Cross-currency swap contract losses	(67)	(179)	Interest and other income, net
Forward interest rate contract losses	—	(1)	Interest expense, net
	19	(175)	Total before income tax
	(7)	64	Tax (expense)/benefit
	$12	$(111)	Net of taxes
Available-for-sale securities:			
Net realized losses	$(39)	$(11)	Interest and other income, net
	15	4	Tax benefit
	$(24)	$(7)	Net of taxes

Components of AOCI	Amounts reclassified out of AOCI Nine months ended September 30, 2015	Nine months ended September 30, 2014	Line item affected in the Statements of Income
Cash flow hedges:			
Foreign currency contract gains	$246	$5	Product sales
Cross-currency swap contract losses	(114)	(117)	Interest and other income, net
Forward interest rate contract losses	(1)	(1)	Interest expense, net
	131	(113)	Total before income tax
	(47)	41	Tax (expense)/benefit
	$84	$(72)	Net of taxes
Available-for-sale securities:			
Net realized (losses) gains	$(83)	$31	Interest and other income, net
	31	(12)	Tax benefit/(expense)
	$(52)	$19	Net of taxes

11. Fair value measurement

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

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

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

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

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

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

Fair value measurement as of September 30, 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	$ 4,291	$—	$—	$4,291
Other government-related debt securities:				
U.S.	—	707	—	707
Foreign and other	—	1,689	—	1,689
Corporate debt securities:				
Financial	—	8,120	—	8,120
Industrial	—	8,054	—	8,054
Other	—	877	—	877
Residential mortgage-backed securities	—	1,516	—	1,516
Other mortgage- and asset-backed securities	—	2,217	—	2,217
Money market mutual funds	2,661	—	—	2,661
Other short-term interest-bearing securities	—	533	—	533
Equity securities	135	—	—	135
Derivatives:				
Foreign currency contracts	—	119	—	119
Interest rate swap contracts	—	160	—	160
Total assets	$ 7,087	$23,992	$—	$31,079
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$5	$—	$5
Cross-currency swap contracts	—	174	—	174
Contingent consideration obligations in connection with business combinations	—	—	197	197
Total liabilities	$ —	$179	$197	$376

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

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

Most of our other government-related and corporate debt securities are investment grade with maturity dates of five years or less from the balance sheet date. Our other government-related debt securities portfolio consists 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 consists entirely of senior tranches, with credit ratings of AAA or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and

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

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

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

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

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

Contingent consideration obligations

We have incurred contingent consideration obligations as a result of our acquisition of a business and upon the assumption of contingent consideration obligations incurred by an acquired company discussed below. These contingent consideration obligations are recorded at their estimated fair values, and we revalue these obligations each reporting period until the related contingencies are resolved. The fair value measurements of these obligations are based on significant unobservable inputs related to product candidates acquired in the business combinations and are reviewed quarterly by management in our R&D and commercial sales organizations. These inputs include, as applicable, estimated probabilities and timing of achieving specified regulatory and commercial milestones and estimated annual sales. Significant changes which increase or decrease the probabilities of achieving the related regulatory and commercial events, shorten or lengthen the time required to achieve such events, or increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of these obligations, as applicable. Changes in fair values of contingent consideration obligations are recognized in Other operating expenses in the 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,	
	2015	2014	2015	2014
Beginning balance	$215	$610	$215	$595
Net changes in valuation	(18)	(62)	(18)	(47)
Ending balance	$197	$548	$197	$548

As a result of our acquisition of BioVex in March 2011, we were obligated to pay its former shareholders up to $575 million of additional consideration contingent upon achieving separate regulatory and sales-related milestones with regard to IMLYGIC™, which was acquired in the acquisition. As a result of filing a Biologics License Application (BLA) in the United States, we made a milestone payment of $125 million to the former BioVex shareholders during 2014. The remaining potential milestone payments include: (i) $125 million upon the first commercial sale in the United States following receipt of marketing approval for use of the product in specified patient populations and (ii) up to $325 million of additional payments of varying amounts upon achievement of certain other regulatory and sales-related milestones.

We estimate the fair values of the obligations to the former shareholders of BioVex by using probability-adjusted discounted cash flows and review underlying key assumptions on a quarterly basis. As a result of these quarterly reviews, the estimated aggregate fair value of the contingent consideration decreased by $18 million during the three and nine months ended September 30, 2015.

As a result of our acquisition of Onyx in October 2013, we assumed contingent consideration obligations arising from Onyx's 2009 acquisition of Proteolix, Inc. These contingent consideration obligations consisted of two separate milestone payments of $150 million each payable if Kyprolis® received specified marketing approvals for relapsed multiple myeloma on or before March 31, 2016, by each of the FDA and the European Medicines Agency (EMA). In December 2014, we renegotiated the terms of these

milestones and settled the contingent consideration obligations with the former shareholders of Proteolix, Inc. by agreeing to make a single payment of $225 million. This amount was paid during the first quarter of 2015.

During the nine months ended September 30, 2015 and 2014, there were no transfers of assets or liabilities between the 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 value of other financial instruments

Cash equivalents

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

Borrowings

We estimated the fair value of our long-term debt (Level 2) by taking into consideration indicative prices obtained from a third-party financial institution that utilizes industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; credit spreads; benchmark yields; foreign currency exchange rates, as applicable; and other observable inputs. As of September 30, 2015, and December 31, 2014, the aggregate fair values of our long-term debt were $33.5 billion and $33.6 billion, respectively, and the carrying values were $31.8 billion and $30.7 billion, respectively.

12. Derivative instruments

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

Cash flow hedges

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

As of September 30, 2015, and December 31, 2014, we had open foreign currency forward contracts with notional amounts of $3.1 billion and $3.8 billion, respectively, and open foreign currency option contracts with notional amounts of $242 million and $271 million, respectively. We have designated these foreign currency forward and option contracts, primarily euro based, as cash flow hedges, and accordingly, we report the effective portions of the unrealized gains and losses on these contracts in AOCI on the Condensed Consolidated Balance Sheets and reclassify them to earnings in the same periods during which the hedged transactions affect earnings.

To manage counterparty risk resulting from favorable movements in U.S. dollar/foreign currency exchange rates, we effectively terminated outstanding foreign currency forward and option contracts with a notional amount of $600 million during the three months ended September 30, 2015, and, we effectively terminated outstanding foreign currency forward contracts with a notional amount of $1.7 billion during the three months ended June 30, 2015. During the three months ended September 30, 2015 and June 30, 2015, we received $90 million and $247 million, respectively, from the counterparties, which was included in Net cash provided by operating activities in the Condensed Consolidated Statement of Cash Flows. This amount remains in AOCI and will be recognized in Product sales in the Condensed Consolidated Statements of Income when the related international product sales affect earnings. In addition, during the three months ended September 30, 2015 and June 30, 2015, we entered into new foreign currency forward and option contracts that hedge these forecasted international product sales. These contracts are included in the notional amounts of cash flow hedges outstanding as of September 30, 2015.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. Under the terms of these contracts, we paid euros/pounds sterling and received U.S. dollars for the notional amounts at the inception of the contracts, and we exchange interest payments

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

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

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

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	2015	2014	2015	2014
Foreign currency contracts	$53	$291	$346	$291
Cross-currency swap contracts	(118)	(104)	(199)	(79)
Total	$(65)	$187	$147	$212

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

		Three months ended September 30,		Nine months ended September 30,	
Derivatives in cash flow hedging relationships	Statements of Income location	2015	2014	2015	2014
Foreign currency contracts	Product sales	$86	$5	$246	$5
Cross-currency swap contracts	Interest and other income, net	(67)	(179)	(114)	(117)
Forward interest rate contracts	Interest expense, net	—	(1)	(1)	(1)
Total		$19	$(175)	$131	$(113)

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, 2015 and 2014. As of September 30, 2015, the amounts expected to be reclassified out of AOCI into earnings over the next 12 months are approximately $302 million of net gains on our foreign currency and cross-currency swap contracts and approximately $1 million of losses on forward interest rate contracts.

Fair value hedges

To achieve a desired mix of fixed and floating interest rates on our long-term debt, we entered into interest rate swap contracts, which qualified and are designated as fair value hedges. The terms of these interest rate swap contracts correspond to the related hedged debt instruments and effectively converted a fixed interest rate coupon to a floating LIBOR-based coupon over the lives of the respective notes. We had interest rate swap agreements as of September 30, 2015 and December 31, 2014, 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 for and are designated as fair value hedges, we recognize in current earnings the unrealized gain or loss on the derivative resulting from the change in fair value during the period as well as the

offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. For the three and nine months ended September 30, 2015, we included the unrealized losses on 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. For the three and nine months ended September 30, 2014, we included the unrealized gains on the hedged debt of $36 million and the unrealized losses of $89 million, respectively, in the same line item, Interest expense, net, in the Condensed Consolidated Statements of Income, as the offsetting unrealized losses of $36 million and unrealized gains of $89 million, respectively, on the related interest rate swap agreements.

Derivatives not designated as hedges

We enter into foreign currency forward contracts that are not designated as hedging transactions to reduce our exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies. These exposures are hedged on a month-to-month basis. As of September 30, 2015, and December 31, 2014, the total notional amounts of these foreign currency forward contracts were $809 million and $875 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 September 30,		Nine months ended September 30,	
Derivatives not designated as hedging instruments	Statements of Income location	2015	2014	2015	2014
Foreign currency contracts	Interest and other income, net	$9	$25	$—	$13

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

	Derivative assets		Derivative liabilities	
September 30, 2015	Balance Sheet location	Fair value	Balance Sheet location	Fair value
Derivatives designated as hedging instruments:				
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	$—	Accrued liabilities/ Other noncurrent liabilities	$174
Foreign currency contracts	Other current assets/ Other noncurrent assets	119	Accrued liabilities/ Other noncurrent liabilities	4
Interest rate swap contracts	Other current assets/ Other noncurrent assets	160	Accrued liabilities/ Other noncurrent liabilities	—
Total derivatives designated as hedging instruments		279		178
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		$279		$179

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

Our derivative contracts that were in liability positions as of September 30, 2015, contain certain credit-risk-related contingent provisions that would be triggered if: (i) we were to undergo a change in control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due to or from a counterparty under these contracts may only be offset against other amounts due to or from the same counterparty if an event of default or termination, as defined, were to occur.

The cash flow effects of our derivative contracts for the nine months ended September 30, 2015 and 2014, 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 and other matters—including those discussed in this Note—that are complex in nature and have outcomes that are difficult to predict. See Note 18, Contingencies and commitments, to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2014, Note 12, Contingencies and commitments, to our condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2015, and Note 13, Contingencies and commitments, to our condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended June 30, 2015, for further discussion of certain of our legal proceedings and other matters.

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

Our legal proceedings range from cases brought by a single plaintiff to class actions with thousands of putative class members. These legal proceedings, as well as other matters, involve various aspects of our business and a variety of claims—including but not limited to patent infringement, marketing, pricing and trade practices and securities law—some

of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing 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, 2014, or in Note 12, Contingencies and commitments, to our condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2015 or in Note 13, Contingencies and commitments, to our condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended June 30, 2015, 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 described in this filing have progressed sufficiently through discovery and/or development of important

factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

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

Biosimilars Patent Litigations

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

Sandoz Filgrastim Litigation

As previously disclosed, this lawsuit stems from Sandoz Inc. (Sandoz), a subsidiary of Novartis AG (Novartis), filing an application for FDA licensure of a filgrastim product as biosimilar to Amgen's NEUPOGEN® (filgrastim) under the BPCIA. On August 20, 2015, Amgen Inc. and Amgen Manufacturing, Limited (collectively Amgen) and Sandoz each petitioned the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court) requesting rehearing en banc of various aspects of the Federal Circuit Court opinion on which the other had prevailed. On October 16, 2015, the Federal Circuit Court denied each of Amgen's and Sandoz's petitions for rehearing en banc.

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

Apotex Pegfilgrastim Litigation

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

On October 16, 2015, Amgen filed a motion for preliminary injunction seeking an order prohibiting Apotex from commercializing its biosimilar pegfilgrastim product until a date that is at least 180 days after Apotex provides legally effective commercial notice to Amgen. The motion is scheduled to be heard by the court on December 4, 2015.

Apotex Filgrastim Litigation

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

Hospira Epoetin Alfa Litigation

On September 18, 2015, Amgen filed a lawsuit in the U.S. District Court for the District of Delaware (the Delaware District Court) against Hospira, Inc. (Hospira), a subsidiary of Pfizer Inc. (Pfizer), for infringement of U.S. Patent Nos. 5,856,298 (the `298 Patent) and 5,756,349 (the `349 Patent) in accordance with the patent provisions of the BPCIA and for a declaration that Hospira has failed to comply with the disclosure and notice requirements of the

BPCIA. This lawsuit stems from the submission by Hospira under the BPCIA of an application for FDA licensure of an epoetin product as biosimilar to Amgen's EPOGEN® (epoetin alfa). Amgen seeks a declaration that the BPCIA requires that Hospira provide Amgen with notice of commercial marketing

180 days before it first begins commercial marketing of any biosimilar epoetin product and that this notice can only be given after the FDA has licensed Hospira's biosimilar product. By its complaint, Amgen seeks, amongst other remedies, an injunction prohibiting Hospira from using or selling infringing cells and/or product manufactured during the `349 or the `298 patent terms and enjoining Hospira from commencing commercial marketing of any biosimilar epoetin product until a date that is at least 180 days after Hospira provides legally effective notice to Amgen.
On October 13, 2015, Hospira filed a motion to dismiss the two counts of Amgen's complaint which seek a declaration that Hospira has failed to comply with the disclosure and notice requirements of the BPCIA.
Sanofi/Regeneron Patent Litigation
Following a claim construction hearing, the Delaware District Court issued an order on October 20, 2015 construing certain terms of the asserted patents in this patent infringement case.
ERISA Litigation
On September 3, 2015, Amgen filed a petition for certiorari with the U.S. Supreme Court and, on September 24, 2015, plaintiff Harris waived his right to respond to the U.S. Supreme Court petition in this Employee Retirement Income Security Act (ERISA) class action case.
14. Subsequent event
On October 14, 2015, we acquired Dezima Pharma B.V. (Dezima), a privately held Netherlands based biotechnology company focused on developing innovative treatments for dyslipidemia, including Dezima's lead molecule TA-8995, an oral, once-daily cholesteryl ester transfer protein inhibitor that recently completed a phase 2b clinical trial. Amgen paid $300 million in cash at closing and will make up to $1.25 billion in additional payments if certain development and sales milestones are achieved. Low single-digit royalties will be paid on net product sales above a certain threshold.

This transaction will be accounted for as a business combination. Given the timing of the closing of the transaction, we are not yet able to provide the amounts to be recognized as of the acquisition date for the assets acquired and liabilities assumed as well as other related disclosures.

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, 2014 and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2015, and June 30, 2015. 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 and planned dividends, stock repurchases and restructuring plans. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology. Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Currently, we market primarily recombinant protein therapeutics for supportive cancer care, inflammation, nephrology, and bone health. Our principal products are Enbrel® (etanercept), Neulasta® (pegfilgrastim), EPOGEN® (epoetin alfa), Aranesp® (darbepoetin alfa), XGEVA® (denosumab), Sensipar®/Mimpara® (cinacalcet), Prolia® (denosumab), and NEUPOGEN® (filgrastim). Our product sales outside the United States consist principally of sales in Europe. For the three and nine months ended September 30, 2015, our principal products represented 91% of worldwide product sales. We market several other products, including Vectibix® (panitumumab), Nplate® (romiplostim), Kyprolis® (carfilzomib), BLINCYTO® (blinatumomab), Corlanor® (ivabradine) and Repatha™ (evolocumab).

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, 2015. 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, 2014 and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2015 and June 30, 2015.

Products/Pipeline

Cardiovascular

Repatha™

- In August 2015, we announced that the FDA granted approval of Repatha™ Injection as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of low density lipoprotein cholesterol (LDL-C); and as an adjunct to diet and other LDL-lowering therapies for the treatment of patients with homozygous familial hypercholesterolemia, who require additional lowering of LDL-C. The effect of Repatha on cardiovascular morbidity and mortality has not been determined.
- In September 2015, we announced that we submitted an application to the FDA for a single-dosing option for the monthly administration of Repatha™ Injection. The FDA has set a July 10, 2016, Prescription Drug User Fee Act (PDUFA) target action date as a goal for the completion of their review of our application.

Nephrology

Etelcalcetide (formerly AMG 416)

- In August 2015, we announced that we submitted a New Drug Application to the FDA for etelcalcetide for the treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) on hemodialysis.
- In September 2015, we announced that we submitted a Marketing Authorization Application to the EMA via the centralized procedure for etelcalcetide for the treatment of SHPT in adult patients with CKD on hemodialysis.

Oncology

BLINCYTO®

- In September 2015, we announced that the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion recommending conditional marketing authorization for BLINCYTO® for the treatment of adults with Philadelphia chromosome-negative relapsed or refractory B-precursor acute lymphoblastic leukemia.

IMLYGIC™ (talimogene laherparepvec)

- In October 2015, we announced that the CHMP of the EMA adopted a positive opinion recommending that IMLYGIC™ be granted marketing authorization for the treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease.
- In October 2015, we announced that the FDA granted approval of IMLYGIC™ for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery. IMLYGIC™ has not been shown to improve overall survival or have an effect on visceral metastases.

Kyprolis®

- In September 2015, we announced that the FDA accepted for priority review the supplemental New Drug Application of Kyprolis® for Injection for patients with relapsed multiple myeloma based on data from the ENDEAVOR (RandomizEd, OpeN Label, Phase 3 Study of Carfilzomib Plus DExamethAsone Vs Bortezomib Plus DexamethasOne in Patients With Relapsed Multiple Myeloma) trial. The PDUFA target action date is January 22, 2016.
- In September 2015, we announced that the CHMP of the EMA adopted a positive opinion recommending marketing authorization for Kyprolis® in combination with lenalidomide and dexamethasone for the treatment of adult patients with relapsed multiple myeloma who have received at least one prior therapy, based on data from the ASPIRE (CArfilzomib, Lenalidomide, and DexamethaSone versus Lenalidomide and Dexamethasone for the treatment of PatIents with Relapsed Multiple MyEloma) trial.

Romosozumab

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

Biosimilars

- In September 2015, we and Allergan plc, our collaboration partner in the development and commercialization of biosimilar candidate ABP 215, announced that a Phase 3 study of ABP 215 compared with Avastin® (bevacizumab) met its primary and secondary endpoints.

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,		
	2015	2014	Change	2015	2014	Change
Product sales:						
U.S.	$4,425	$3,682	20 %	$12,301	$10,729	15 %
Rest of the world (ROW)	1,091	1,166	(6)%	3,314	3,424	(3)%
Total product sales	5,516	4,848	14 %	15,615	14,153	10 %
Other revenues	207	183	13 %	511	579	(12)%
Total revenues	$5,723	$5,031	14 %	$16,126	$14,732	9 %
Operating expenses	$3,384	$3,565	(5)%	$9,689	$10,000	(3)%
Operating income	$2,339	$1,466	60 %	$6,437	$4,732	36 %
Net income	$1,863	$1,244	50 %	$5,139	$3,864	33 %
Diluted EPS	$2.44	$1.61	52 %	$6.70	$5.02	33 %
Diluted shares	764	771	(1)%	767	769	— %

The increases in global product sales for the three and nine months ended September 30, 2015, were driven by ENBREL, Prolia®, Sensipar®, XGEVA®, Neulasta® and Kyprolis®.

The decreases in operating expenses for the three and nine months ended September 30, 2015, were driven primarily by higher restructuring charges in the prior year as well as savings from transformation and process improvement efforts, offset partially by increased support for launch products.

Increases in net income and diluted EPS for the three and nine months ended September 30, 2015, were driven by increases in revenues and operating income.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is offset partially by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impacts from changes in foreign currency exchange rates were not material for the three and nine months ended September 30, 2015 and 2014.

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,			
	2015	2014	Change		2015	2014	Change	
ENBREL	$1,459	$1,120	30	%	$3,923	$3,351	17	%
Neulasta®	1,267	1,193	6	%				