UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value	**AMGN**	**The NASDAQ Global Select Market**
1.250% Senior Notes Due 2022	**AMGN22**	**New York Stock Exchange**
2.00% Senior Notes Due 2026	**AMGN26**	**New York Stock Exchange**

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

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

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

Large accelerated filer	Accelerated filer	Non-accelerated filer
Smaller reporting company	Emerging growth company	

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes

No

As of October 23, 2019, the registrant had 594,183,541 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,	
	2019	2018	2019	2018
Revenues:				
Product sales	$ 5,463	$ 5,510	$ 16,323	$ 16,532
Other revenues	274	394	842	985
Total revenues	5,737	5,904	17,165	17,517
Operating expenses:				
Cost of sales	1,036	1,037	3,103	3,005
Research and development	1,001	926	2,804	2,555
Selling, general and administrative	1,223	1,293	3,637	3,773
Other	1	325	(5)	303
Total operating expenses	3,261	3,581	9,539	9,636
Operating income	2,476	2,323	7,626	7,881
Interest expense, net	313	355	988	1,040
Interest and other income, net	114	126	517	519
Income before income taxes	2,277	2,094	7,155	7,360
Provision for income taxes	309	235	1,016	894
Net income	$ 1,968	$ 1,859	$ 6,139	$ 6,466
Earnings per share:				
Basic	$ 3.29	$ 2.88	$ 10.08	$ 9.67
Diluted	$ 3.27	$ 2.86	$ 10.01	$ 9.61
Shares used in calculation of earnings per share:				
Basic	599	645	609	669
Diluted	602	649	613	673

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net income	$ 1,968	$ 1,859	$ 6,139	$ 6,466
Other comprehensive income (loss), net of reclassification adjustments and taxes:				
Losses on foreign currency translation	(39)	(71)	(56)	(153)
Gains on cash flow hedges	86	41	27	270
Gains (losses) on available-for-sale securities	30	97	404	(237)
Other	—	(3)	6	(1)
Other comprehensive income (loss), net of taxes	77	64	381	(121)
Comprehensive income	$ 2,045	$ 1,923	$ 6,520	$ 6,345

See accompanying notes.

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

	September 30, 2019	December 31, 2018
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,415	$ 6,945
Marketable securities	9,438	22,359
Trade receivables, net	3,606	3,580
Inventories	3,243	2,940
Other current assets	3,349	1,794
Total current assets	31,051	37,618
Property, plant and equipment, net	4,901	4,958
Intangible assets, net	6,702	7,443
Goodwill	14,705	14,699
Other assets	2,176	1,698
Total assets	$ 59,535	$ 66,416
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,005	$ 1,207
Accrued liabilities	7,683	7,862
Current portion of long-term debt	2,049	4,419
Total current liabilities	10,737	13,488
Long-term debt	27,742	29,510
Long-term deferred tax liabilities	665	864
Long-term tax liabilities	7,921	8,770
Other noncurrent liabilities	1,543	1,284
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding — 596.2 shares in 2019 and 629.6 shares in 2018	31,451	31,246
Accumulated deficit	(20,136)	(17,977)
Accumulated other comprehensive loss	(388)	(769)
Total stockholders' equity	10,927	12,500
Total liabilities and stockholders' equity	$ 59,535	$ 66,416

See accompanying notes.

AMGEN INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In millions, except per-share data)
(Unaudited)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of December 31, 2018	629.6	$ 31,246	$ (17,977)	$ (769)	$ 12,500
Net income	—	—	1,992	—	1,992
Other comprehensive income, net of taxes	—	—	—	253	253
Dividends declared on common stock ($1.45 per share)	—	—	(879)	—	(879)
Issuance of common stock in connection with the Company's equity award programs	0.7	6	—	—	6
Stock-based compensation expense	—	64	—	—	64
Tax impact related to employee stock-based compensation expense	—	(73)	—	—	(73)
Repurchases of common stock	(15.9)	—	(3,031)	—	(3,031)
Balance as of March 31, 2019	614.4	31,243	(19,895)	(516)	10,832
Net income	—	—	2,179	—	2,179
Other comprehensive income, net of taxes	—	—	—	51	51
Issuance of common stock in connection with the Company's equity award programs	0.8	23	—	—	23
Stock-based compensation expense	—	97	—	—	97
Tax impact related to employee stock-based compensation expense	—	(50)	—	—	(50)
Repurchases of common stock	(13.1)	—	(2,349)	—	(2,349)
Other	—	—	11	—	11
Balance as of June 30, 2019	602.1	31,313	(20,054)	(465)	10,794
Net income	—	—	1,968	—	1,968
Other comprehensive income, net of taxes	—	—	—	77	77
Dividends declared on common stock ($1.45 per share)	—	—	(880)	—	(880)
Issuance of common stock in connection with the Company's equity award programs	0.3	37	—	—	37
Stock-based compensation expense	—	108	—	—	108
Tax impact related to employee stock-based compensation expense	—	(7)	—	—	(7)
Repurchases of common stock	(6.2)	—	(1,170)	—	(1,170)
Balance as of September 30, 2019	596.2	$ 31,451	$ (20,136)	$ (388)	$ 10,927

See accompanying notes.

AMGEN INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In millions, except per-share data)
(Unaudited)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of December 31, 2017	722.2	$ 30,992	$ (5,072)	$ (679)	$ 25,241
Cumulative effect of changes in accounting principles, net of taxes	—	—	38	(9)	29
Net income	—	—	2,311	—	2,311
Other comprehensive loss, net of taxes	—	—	—	(306)	(306)
Dividends declared on common stock ($1.32 per share)	—	—	(877)	—	(877)
Issuance of common stock in connection with the Company's equity award programs	0.6	5	—	—	5
Stock-based compensation expense	—	61	—	—	61
Tax impact related to employee stock-based compensation expense	—	(57)	—	—	(57)
Repurchases of common stock	(56.4)	—	(10,787)	—	(10,787)
Balance as of March 31, 2018	666.4	31,001	(14,387)	(994)	15,620
Net income	—	—	2,296	—	2,296
Other comprehensive income, net of taxes	—	—	—	121	121
Issuance of common stock in connection with the Company's equity award programs	0.8	19	—	—	19
Stock-based compensation expense	—	93	—	—	93
Tax impact related to employee stock-based compensation expense	—	(65)	—	—	(65)
Repurchases of common stock	(18.2)	—	(3,190)	—	(3,190)
Other	—	—	15	—	15
Balance as of June 30, 2018	649.0	31,048	(15,266)	(873)	14,909
Net income	—	—	1,859	—	1,859
Other comprehensive income, net of taxes	—	—	—	64	64
Dividends declared on common stock ($1.32 per share)	—	—	(867)	—	(867)
Issuance of common stock in connection with the Company's equity award programs	0.2	13	—	—	13
Stock-based compensation expense	—	94	—	—	94
Tax impact related to employee stock-based compensation expense	—	(10)	—	—	(10)
Repurchases of common stock	(8.7)	—	(1,713)	—	(1,713)
Balance as of September 30, 2018	640.5	$ 31,145	$ (15,987)	$ (809)	$ 14,349

See accompanying notes.

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

	Nine months ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net income	$ 6,139	$ 6,466
Depreciation, amortization and other	1,504	1,456
Deferred income taxes	(172)	(294)
Other items, net	169	636
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	(63)	(234)
Inventories	(101)	(93)
Other assets	(269)	(110)
Accounts payable	(196)	(311)
Accrued income taxes, net	(128)	(384)
Long-term tax liabilities	(262)	204
Other liabilities	15	766
Net cash provided by operating activities	6,636	8,102
Cash flows from investing activities:		
Purchases of marketable securities	(9,062)	(12,617)
Proceeds from sales of marketable securities	3,019	28,059
Proceeds from maturities of marketable securities	18,441	3,881
Cash paid, net of cash acquired	(177)	197
Purchases of property, plant and equipment	(430)	(513)
Other	(119)	(31)
Net cash provided by investing activities	11,672	18,976
Cash flows from financing activities:		
Repayment of debt	(4,514)	(500)
Repurchases of common stock	(6,608)	(15,670)
Dividends paid	(2,649)	(2,667)
Other	(67)	(85)
Net cash used in financing activities	(13,838)	(18,922)
Increase in cash and cash equivalents	4,470	8,156
Cash and cash equivalents at beginning of period	6,945	3,800
Cash and cash equivalents at end of period	$ 11,415	$ 11,956

See accompanying notes.

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, 2019 and 2018, 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, 2018, 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, 2019 and June 30, 2019.

Principles of consolidation

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

Use of estimates

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

Property, plant and equipment, net

Property, plant and equipment is recorded at historical cost, net of accumulated depreciation and amortization of $8.2 billion and $7.8 billion as of September 30, 2019 and December 31, 2018, respectively.

Leases

Adoption of new lease standard

In February 2016, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the accounting and disclosure of leases. This new standard requires that lessees recognize the assets and liabilities that arise from leases on the balance sheet, including leases classified as operating leases, and that they disclose qualitative and quantitative information about leasing arrangements. The FASB subsequently issued additional amendments to address issues arising from the implementation of the new lease standard. We adopted this standard as of January 1, 2019, using the modified-retrospective method. This approach provides a method for recording existing leases at adoption. We used the adoption date as our date of initial application, and thus, comparative-period financial information is not presented for periods prior to the adoption date. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed us to carry forward the historical lease classification.

Adoption of the new standard resulted in total lease liabilities of $510 million and right-of-use (ROU) assets of $439 million as of January 1, 2019. The difference between the initial lease liabilities and the ROU assets is related primarily to previously existing lease liabilities. The standard did not materially impact our Condensed Consolidated Statements of Income and had no impact on our Condensed Consolidated Statements of Cash Flows. Our accounting policies under the new standard are described below. See Note 9, Leases.

Lease recognition

At inception of a contract, we determine whether an arrangement is or contains a lease. For all leases, we determine the classification as either operating or financing. Operating leases are included in Other assets, Accrued liabilities and Other noncurrent liabilities in our Condensed Consolidated Balance Sheets.

ROU assets represent our right to use an underlying asset for the lease term, and lease liabilities represent our obligation to make lease payments under the lease. Lease recognition occurs at the commencement date, and lease liability amounts are based on the present value of lease payments made during the lease term. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Because most of our leases do not provide information to determine an implicit interest rate, we use our incremental borrowing rate in determining the present value of lease payments. ROU assets also include any lease payments made prior to the commencement date and exclude lease incentives received. Operating lease expense is recognized on a straight-line basis over the lease term.

We have lease agreements with both lease and nonlease components, which are generally accounted for together as a single lease component. In addition, for certain vehicle and equipment leases, we apply a portfolio approach to determine the lease term and discount rate.

Other recent accounting pronouncements

In June 2016, the FASB issued a new accounting standard that amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the incurred-loss model with an expected-loss model. Accordingly, these financial assets will be presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than by 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. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. We have substantially completed our impact assessment and do not currently anticipate a material impact on our condensed consolidated financial statements.

2. Business combinations

Nuevolution AB

On July 15, 2019, we acquired all of the outstanding stock of Nuevolution AB (Nuevolution), a publicly traded, Denmark-based biotechnology company with a leading small-molecule-drug discovery platform, for total consideration of $183 million in cash. The transaction, which was accounted for as a business combination, expands our ability to discover novel small molecules against difficult-to-drug targets and with greater speed and efficiency. Nuevolution's operations, which are not material, have been included in our condensed consolidated financial statements commencing on the acquisition date.

We allocated the consideration to acquire Nuevolution to finite-lived intangible assets of $150 million, comprised primarily of technology rights for a drug discovery platform with an estimated useful life of 10 years; goodwill of $26 million, which is not tax deductible; deferred tax liabilities of $22 million; and other net assets of $29 million.

The estimated fair values of intangible assets were determined primarily using a probability-weighted income approach, which discounts expected future cash flows to present value by using a discount rate that represents the estimated rate that market participants would use to value the intangible assets.

Our accounting for this acquisition is preliminary and will be finalized upon completion of our analysis to determine the acquisition date fair values of certain assets acquired, tax-related items and the residual impact on goodwill.

Otezla®

On August 25, 2019, we entered into an agreement with Celgene Corporation (Celgene) in connection with Celgene's previously announced merger with Bristol-Myers Squibb Company (BMS) to acquire worldwide rights to Otezla® (apremilast), the only oral, nonbiologic treatment for psoriasis and psoriatic arthritis, and certain related assets and liabilities for $13.4 billion. We expect to fund the purchase price with cash. The transaction is expected to close by the end of 2019.

3. Revenues

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

Revenues were as follows (in millions):

	Three months ended September 30,					
	2019			2018		
	US	ROW	Total	US	ROW	Total
Enbrel® (etanercept)	$ 1,323	$ 43	$ 1,366	$ 1,242	$ 50	$ 1,292
Neulasta® (pegfilgrastim)	619	92	711	897	154	1,051
Prolia® (denosumab)	425	205	630	354	178	532
XGEVA® (denosumab)	356	120	476	323	110	433
Aranesp® (darbepoetin alfa)	204	248	452	248	229	477
KYPROLIS® (carfilzomib)	163	103	266	142	90	232
EPOGEN® (epoetin alfa)	215	—	215	252	—	252
Sensipar®/Mimpara® (cinacalcet)	38	71	109	330	79	409
Other products	686	552	1,238	472	360	832
Total product sales[1]	$ 4,029	$ 1,434	5,463	$ 4,260	$ 1,250	5,510
Other revenues			274			394
Total revenues			$ 5,737			$ 5,904

	Nine months ended September 30,					
	2019			2018		
	US	ROW	Total	US	ROW	Total
ENBREL	$ 3,744	$ 136	$ 3,880	$ 3,544	$ 155	$ 3,699
Neulasta®	2,231	325	2,556	2,854	452	3,306
Prolia®	1,273	647	1,920	1,070	566	1,636
XGEVA®	1,091	355	1,446	994	336	1,330
Aranesp®	578	724	1,302	714	689	1,403
KYPROLIS®	483	295	778	430	287	717
EPOGEN®	657	—	657	746	—	746
Sensipar®/Mimpara®	216	228	444	1,069	257	1,326
Other products	1,889	1,451	3,340	1,353	1,016	2,369
Total product sales[1]	$ 12,162	$ 4,161	16,323	$ 12,774	$ 3,758	16,532
Other revenues			842			985
Total revenues			$ 17,165			$ 17,517

[1] Hedging gains and losses, which are included in product sales, were not material for the three andnine months ended September 30, 2019 and 2018.

4. Income taxes

Effective tax rates for the three and nine months ended September 30, 2019, were 13.6% and 14.2%, respectively, compared with 11.2% and 12.1%, respectively, for the corresponding periods of the prior year.

The increases in our effective tax rates for the three and nine months ended September 30, 2019, were due primarily to a prior-year tax benefit associated with intercompany sales under U.S. corporate tax reform. The effective tax rates differ from the federal statutory rate primarily as a result of foreign earnings from the Company's operations conducted in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes and that is subject to tax incentive grants through 2035; these earnings are subject to U.S. tax at a reduced rate of 10.5%.

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

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes may arise with authorities involving issues of the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and relevant facts. As previously disclosed, we received a Revenue Agent Report (RAR) from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Final resolution of this complex matter is not likely within the next 12 months and could have a material impact on our condensed consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009. In addition, we are currently under examination by a number of other state and foreign tax jurisdictions.

During the three and nine months ended September 30, 2019, the gross amounts of our unrecognized tax benefits (UTBs) increased $50 million and $160 million, respectively, as a result of tax positions taken during the current year. Substantially all of the UTBs as of September 30, 2019, 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 (collectively, dilutive securities), as determined by using the treasury stock method.

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,	
	2019	2018	2019	2018
Income (Numerator):				
Net income for basic and diluted EPS	$ 1,968	$ 1,859	$ 6,139	$ 6,466
Shares (Denominator):				
Weighted-average shares for basic EPS	599	645	609	669
Effect of dilutive securities	3	4	4	4
Weighted-average shares for diluted EPS	602	649	613	673
Basic EPS	$ 3.29	$ 2.88	$ 10.08	$ 9.67
Diluted EPS	$ 3.27	$ 2.86	$ 10.01	$ 9.61

For the three and nine months ended September 30, 2019 and 2018, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

6. Investments

Available-for-sale investments

The amortized cost, gross unrealized gains, gross unrealized losses and fair values of interest-bearing securities, which are considered available-for-sale, by type of security were as follows (in millions):

Types of securities as of September 30, 2019	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 1,164	$ 3	$ —	$ 1,167
U.S. Treasury bills	2,494	—	—	2,494
Other government-related debt securities:				
U.S.	—	—	—	—
Foreign and other	896	29	—	925
Corporate debt securities:				
Financial	2,116	24	—	2,140
Industrial	2,002	23	—	2,025
Other	531	6	—	537
Residential-mortgage-backed securities	512	4	—	516
Other mortgage- and asset-backed securities	43	—	—	43
Money market mutual funds	8,017	—	—	8,017
Other short-term interest-bearing securities	2,363	—	—	2,363
Total interest-bearing securities	$ 20,138	$ 89	$ —	$ 20,227

Types of securities as of December 31, 2018	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 2,710	$ —	$ (47)	$ 2,663
U.S. Treasury bills	8,191	—	—	8,191
Other government-related debt securities:				
U.S.	112	—	(2)	110
Foreign and other	972	1	(41)	932
Corporate debt securities:				
Financial	2,778	—	(81)	2,697
Industrial	2,603	—	(99)	2,504
Other	583	—	(21)	562
Residential-mortgage-backed securities	1,458	—	(36)	1,422
Other mortgage- and asset-backed securities	483	—	(14)	469
Money market mutual funds	5,659	—	—	5,659
Other short-term interest-bearing securities	3,515	—	—	3,515
Total interest-bearing securities	$ 29,064	$ 1	$ (341)	$ 28,724

The fair values of interest-bearing securities by location in the Condensed Consolidated Balance Sheets were as follows (in millions):

Condensed Consolidated Balance Sheets locations	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 10,789	$ 6,365
Marketable securities	9,438	22,359
Total interest-bearing securities	$ 20,227	$ 28,724

Cash and cash equivalents in the above table excludes bank account cash of $626 million and $580 million as of September 30, 2019 and December 31, 2018, respectively.

The fair values of 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 maturities	September 30, 2019	December 31, 2018
Maturing in one year or less	$ 12,941	$ 17,424
Maturing after one year through three years	4,855	3,356
Maturing after three years through five years	1,226	5,168
Maturing after five years through ten years	646	885
Mortgage- and asset-backed securities	559	1,891
Total interest-bearing securities	$ 20,227	$ 28,724

For the three months ended September 30, 2019 and 2018, realized gains on interest-bearing securities were $21 million and $5 million, respectively, and realized losses on interest-bearing securities were $24 million and $108 million, respectively. For the nine months ended September 30, 2019 and 2018, realized gains on interest-bearing securities were $23 million and $27 million, respectively, and realized losses on interest-bearing securities were $32 million and $379 million, respectively. Realized gains and losses on interest-bearing securities are recorded in Interest and other income, net, in the Condensed Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method. As of September 30, 2019, we had $1.1 billion in receivables related to sales of securities, which were recorded in Other current assets in the Condensed Consolidated Balance Sheets. There were no receivables related to sales of securities as of December 31, 2018.

As of September 30, 2019, aggregate gross unrealized losses of interest-bearing securities were not material.As of December 31, 2018, the fair values and gross unrealized losses of interest-bearing securities in an unrealized loss position aggregated by type and length of time that the securities have been in a continuous loss position were as follows (in millions):

	Less than 12 months		12 months or more	
Types of securities as of December 31, 2018	**Fair values**	**Unrealized losses**	**Fair values**	**Unrealized losses**
U.S. Treasury notes	$ 1,219	$ (21)	$ 1,444	$ (26)
Other government-related debt securities:				
U.S.	—	—	110	(2)
Foreign and other	631	(31)	240	(10)
Corporate debt securities:				
Financial	1,968	(59)	718	(22)
Industrial	1,898	(81)	529	(18)
Other	529	(20)	28	(1)
Residential-mortgage-backed securities	576	(14)	840	(22)
Other mortgage- and asset-backed securities	17	—	451	(14)
Total	$ 6,838	$ (226)	$ 4,360	$ (115)

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

We review our available-for-sale investments for other-than-temporary declines in fair value below our cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. The evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below our cost basis as well as adverse conditions related specifically to the security, such as 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, 2019 and December 31, 2018, we believe the cost bases for our available-for-sale investments were recoverable in all material respects.

Equity securities

We held investments in equity securities with readily determinable fair values of$277 million and $176 million as of September 30, 2019 and December 31, 2018, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. Gains and losses recognized on equity securities with readily determinable fair values, including gains and losses recognized on sales, were not material for the three and nine months ended September 30, 2019 and 2018.

As of September 30, 2019 and December 31, 2018, respectively, we held investments of $170 million and $222 million in equity securities without readily determinable fair values, which are included in Other assets in the Condensed Consolidated Balance Sheets. Adjustments to the carrying values of these securities were not material for the three and nine months ended September 30, 2019 and 2018.

Limited partnership investments

We held limited partnership investments of $319 million and $285 million as of September 30, 2019 and December 31, 2018, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. These investments are measured by using the net asset values of the underlying investments as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of September 30, 2019, unfunded additional commitments to be made during the next several years for these investments were not material. Gains and losses recognized on our limited partnership investments were not material for the three and nine months ended September 30, 2019 and 2018.

7. Inventories

Inventories consisted of the following (in millions):

	September 30, 2019	December 31, 2018
Raw materials	$ 324	$ 257
Work in process	1,923	1,660
Finished goods	996	1,023
Total inventories	$ 3,243	$ 2,940

8. Goodwill and other intangible assets

Goodwill

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

	Nine months ended September 30, 2019
Beginning balance	$ 14,699
Addition from Nuevolution acquisition	26
Currency translation adjustment	(20)
Ending balance	$ 14,705

Other intangible assets

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

	September 30, 2019			December 31, 2018		
	Gross carrying amounts	Accumulated amortization	Other intangible assets, net	Gross carrying amounts	Accumulated amortization	Other intangible assets, net
Finite-lived intangible assets:						
Developed-product-technology rights	$ 12,548	$ (7,978)	$ 4,570	$ 12,573	$ (7,479)	$ 5,094
Licensing rights	3,761	(2,286)	1,475	3,772	(2,032)	1,740
Marketing-related rights	1,209	(972)	237	1,297	(1,019)	278
Research and development technology rights	1,266	(922)	344	1,148	(872)	276
Total finite-lived intangible assets	18,784	(12,158)	6,626	18,790	(11,402)	7,388
Indefinite-lived intangible assets:						
In-process research and development	76	—	76	55	—	55
Total other intangible assets	$ 18,860	$ (12,158)	$ 6,702	$ 18,845	$ (11,402)	$ 7,443

Developed-product-technology rights consists of rights related to marketed products acquired in business combinations. Licensing rights consists primarily of contractual rights acquired in business combinations to receive future milestone, royalty and profit-sharing payments; capitalized payments to third parties for milestones related to regulatory approvals to commercialize products; and up-front payments associated with royalty obligations for marketed products. Marketing-related rights consists primarily of rights related to the sale and distribution of marketed products. Research and development (R&D) technology rights pertains to technology used in R&D that have alternative future uses. R&D technology rights include assets acquired with the Nuevolution acquisition in 2019. See Note 2, Business combinations.

In-process research and development (IPR&D) consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. We review IPR&D projects for impairment annually, whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable and upon the establishment of technological feasibility or regulatory approval.

During the three months ended September 30, 2019 and 2018, we recognized amortization associated with our finite-lived intangible assets of $318 million and $331 million, respectively. During the nine months ended September 30, 2019 and 2018, we recognized amortization associated with our finite-lived intangible assets of $948 million and $983 million, respectively. Amortization of intangible assets is included primarily in Cost of sales in the Condensed Consolidated Statements of Income. The total estimated amortization for our finite-lived intangible assets for the remaining three months ending December 31, 2019, and the years ending December 31, 2020, 2021, 2022, 2023 and 2024, are $0.3 billion, $1.2 billion, $1.0 billion, $0.9 billion, $0.9 billion and $0.9 billion, respectively.

9. Leases

On January 1, 2019, we adopted a new accounting standard that amends the guidance for the accounting and reporting of leases. Certain required disclosures have been made on a prospective basis in accordance with the guidance of the standard. See Note 1, Summary of significant accounting policies.

We lease certain facilities and equipment related primarily to administrative, R&D and sales and marketing activities. Leases with terms of 12 months or less are expensed on a straight-line basis over the term and are not recorded in the Condensed Consolidated Balance Sheets.

Most leases include one or more options to renew, with renewal terms that may extend the lease term up to seven years. The exercise of lease renewal options is at our sole discretion. In addition, some of our lease agreements include rental payments adjusted periodically for inflation. Our lease agreements neither contain residual value guarantees nor impose significant restrictions or covenants. We sublease certain real estate to third parties. Our sublease portfolio consists of operating leases from former R&D and administrative space.

The following table summarizes information related to our leases, all of which are classified as operating, included in our Condensed Consolidated Balance Sheets (in millions):

Condensed Consolidated Balance Sheets locations	September 30, 2019
Assets:	
Other assets	$ 422
Liabilities:	
Accrued liabilities	$ 135
Other noncurrent liabilities	351
Total lease liabilities	$ 486

The components of net lease costs were as follows (in millions):

Lease costs	Three months ended September 30, 2019	Nine months ended September 30, 2019
Operating[1]	$ 50	$ 149
Sublease income	(8)	(25)
Total net lease costs	$ 42	$ 124

[1] Includes short-term leases and variable lease costs, which were not material for the three and nine months ended September 30, 2019.

Maturities of lease liabilities as of September 30, 2019, were as follows (in millions):

Maturity dates	Operating leases
Remaining three months ending December 31, 2019	$ 31
2020	157
2021	137
2022	77
2023	65
Thereafter	55
Total lease payments[1]	522
Less imputed interest	(36)
Present value of lease liabilities	$ 486

[1] Includes future rental commitments for abandoned leases of $189 million. We expect to receive total future rental income of $149 million related to noncancelable subleases for abandoned facilities.

The weighted-average remaining lease term and weighted-average discount rate of our leases were four years and 3.31%, respectively, as of September 30, 2019.

Cash and noncash information related to our leases was as follows (in millions):

	Three months ended September 30, 2019	Nine months ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 42	$ 115
ROU assets obtained in exchange for lease obligations:		
Operating leases	$ 29	$ 83

10. Financing arrangements

Our borrowings consisted of the following (in millions):

	September 30, 2019	December 31, 2018
5.70% notes due 2019 (5.70% 2019 Notes)	$ —	$ 1,000
1.90% notes due 2019 (1.90% 2019 Notes)	—	700
Floating Rate Notes due 2019	—	550
2.20% notes due 2019 (2.20% 2019 Notes)	—	1,400
2.125% €675 million notes due 2019 (2.125% 2019 euro Notes)	—	774
4.50% notes due 2020 (4.50% 2020 Notes)	300	300
2.125% notes due 2020 (2.125% 2020 Notes)	750	750
Floating Rate Notes due 2020	300	300
2.20% notes due 2020 (2.20% 2020 Notes)	700	700
3.45% notes due 2020 (3.45% 2020 Notes)	900	900
4.10% notes due 2021 (4.10% 2021 Notes)	1,000	1,000
1.85% notes due 2021 (1.85% 2021 Notes)	750	750
3.875% notes due 2021 (3.875% 2021 Notes)	1,750	1,750
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	1,362	1,433
2.70% notes due 2022 (2.70% 2022 Notes)	500	500
2.65% notes due 2022 (2.65% 2022 Notes)	1,500	1,500
3.625% notes due 2022 (3.625% 2022 Notes)	750	750
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	702	713
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
3.125% notes due 2025 (3.125% 2025 Notes)	1,000	1,000
2.00% €750 million notes due 2026 (2.00% 2026 euro Notes)	817	860
2.60% notes due 2026 (2.60% 2026 Notes)	1,250	1,250
5.50% £475 million notes due 2026 (5.50% 2026 pound sterling Notes)	584	606
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	860	893
6.375% notes due 2037 (6.375% 2037 Notes)	552	552
6.90% notes due 2038 (6.90% 2038 Notes)	291	291
6.40% notes due 2039 (6.40% 2039 Notes)	466	466
5.75% notes due 2040 (5.75% 2040 Notes)	412	412
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	974	974
5.65% notes due 2042 (5.65% 2042 Notes)	487	487
5.375% notes due 2043 (5.375% 2043 Notes)	261	261
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(874)	(896)
Fair value adjustments	391	(53)
Total carrying value of debt	29,791	33,929
Less current portion	(2,049)	(4,419)
Total long-term debt	$ 27,742	$ 29,510

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

11. Stockholders' equity

Stock repurchase program

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

	2019		2018	
	Shares	Dollars	Shares *	Dollars
First quarter	15.9	$ 3,031	56.4	$ 10,787
Second quarter	13.1	2,349	18.2	3,190
Third quarter	6.2	1,170	8.7	1,713
Total stock repurchases	35.2	$ 6,550	83.4	$ 15,690

* Total shares do not add due to rounding.

In May 2019, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $5.0 billion. As of September 30, 2019, $3.6 billion of authorization remained available under our stock repurchase program.

Dividends

In August 2019, March 2019 and December 2018, the Board of Directors declared quarterly cash dividends of $1.45 per share, which were paid in September 2019, June 2019 and March 2019, respectively. In October 2019, the Board of Directors declared a quarterly cash dividend of $1.45 per share, which will be paid on December 6, 2019.

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, 2018	$ (670)	$ 241	$ (338)	$ (2)	$ (769)
Foreign currency translation adjustments	(13)	—	—	—	(13)
Unrealized gains	—	30	218	—	248
Reclassification adjustments to income	—	28	4	—	32
Income taxes	—	(13)	(1)	—	(14)
Balance as of March 31, 2019	(683)	286	(117)	(2)	(516)
Foreign currency translation adjustments	(4)	—	—	—	(4)
Unrealized (losses) gains	—	(96)	161	—	65
Reclassification adjustments to income	—	(36)	2	—	(34)
Other	—	—	—	6	6
Income taxes	—	28	(10)	—	18
Balance as of June 30, 2019	(687)	182	36	4	(465)
Foreign currency translation adjustments	(39)	—	—	—	(39)
Unrealized gains	—	71	35	—	106
Reclassification adjustments to income	—	38	3	—	41
Income taxes	—	(23)	(8)	—	(31)
Balance as of September 30, 2019	$ (726)	$ 268	$ 66	$ 4	$ (388)

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

Components of AOCI	Three months ended September 30, 2019	2018	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract gains	$ 26	$ 3	Product sales
Cross-currency swap contract losses	(64)	(36)	Interest and other income, net
	(38)	(33)	Income before income taxes
	8	7	Provision for income taxes
	$ (30)	$ (26)	Net income
Available-for-sale securities:			
Net realized losses	$ (3)	$ (103)	Interest and other income, net
	—	1	Provision for income taxes
	$ (3)	$ (102)	Net income

Components of AOCI	Nine months ended September 30, 2019	2018	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract gains (losses)	$ 62	$ (51)	Product sales
Cross-currency swap contract losses	(92)	(170)	Interest and other income, net
	(30)	(221)	Income before income taxes
	6	47	Provision for income taxes
	$ (24)	$ (174)	Net income
Available-for-sale securities:			
Net realized losses	$ (9)	$ (352)	Interest and other income, net
	—	3	Provision for income taxes
	$ (9)	$ (349)	Net income

12. Fair value measurement

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

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

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

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

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

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

Fair value measurement as of September 30, 2019, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Interest-bearing securities:				
U.S. Treasury notes	$ 1,167	$ —	$ —	$ 1,167
U.S. Treasury bills	2,494	—	—	2,494
Other government-related debt securities:				
U.S.	—	—	—	—
Foreign and other	—	925	—	925
Corporate debt securities:				
Financial	—	2,140	—	2,140
Industrial	—	2,025	—	2,025
Other	—	537	—	537
Residential-mortgage-backed securities	—	516	—	516
Other mortgage- and asset-backed securities	—	43	—	43
Money market mutual funds	8,017	—	—	8,017
Other short-term interest-bearing securities	—	2,363	—	2,363
Equity securities	277	—	—	277
Derivatives:				
Foreign currency contracts	—	339	—	339
Cross-currency swap contracts	—	12	—	12
Interest rate swap contracts	—	354	—	354
Total assets	$ 11,955	$ 9,254	$ —	$ 21,209
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 6	$ —	$ 6
Cross-currency swap contracts	—	478	—	478
Contingent consideration obligations	—	—	62	62
Total liabilities	$ —	$ 484	$ 62	$ 546

Fair value measurement as of December 31, 2018, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Interest-bearing securities:				
U.S. Treasury notes	$ 2,663	$ —	$ —	$ 2,663
U.S. Treasury bills	8,191	—	—	8,191
Other government-related debt securities:				
U.S.	—	110	—	110
Foreign and other	—	932	—	932
Corporate debt securities:				
Financial	—	2,697	—	2,697
Industrial	—	2,504	—	2,504
Other	—	562	—	562
Residential-mortgage-backed securities	—	1,422	—	1,422
Other mortgage- and asset-backed securities	—	469	—	469
Money market mutual funds	5,659	—	—	5,659
Other short-term interest-bearing securities	—	3,515	—	3,515
Equity securities	176	—	—	176
Derivatives:				
Foreign currency contracts	—	182	—	182
Cross-currency swap contracts	—	170	—	170
Interest rate swap contracts	—	56	—	56
Total assets	$ 16,689	$ 12,619	$ —	$ 29,308
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 26	$ —	$ 26
Cross-currency swap contracts	—	401	—	401
Interest rate swap contracts	—	149	—	149
Contingent consideration obligations	—	—	72	72
Total liabilities	$ —	$ 576	$ 72	$ 648

Interest-bearing and equity securities

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

Most of our other government-related and corporate debt securities are investment grade and have maturity dates offive 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 BBB+ 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 weighted-average credit ratings of A– 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 use industry-standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

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

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

Derivatives

All of our foreign currency forward and option derivative contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, the London Interbank Offered Rate (LIBOR), swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. These inputs, when applicable, are at commonly quoted intervals. See Note 13, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency-basis swap spreads. See Note 13, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by using an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include LIBOR, swap rates and obligor credit default swap rates. See Note 13, Derivative instruments.

Contingent consideration obligations

As a result of our business combinations, we have incurred contingent consideration obligations. The contingent consideration obligations are recorded at their fair values by using probability-adjusted discounted cash flows, and we revalue these obligations each reporting period until the related contingencies have been resolved. The fair value measurements of these obligations are based on significant unobservable inputs related to licensing rights and product candidates acquired in business combinations, and they are reviewed quarterly by management in our R&D and commercial sales organizations. 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 for the three and nine months ended September 30, 2019 and 2018, were not material.

During the three and nine months ended September 30, 2019 and 2018, 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, except with respect to the 2018 discontinuance of the internal development of a nonkey program resulting in an impairment of an IPR&D asset of $330 million, which was recognized in Other operating expenses in the Condensed Consolidated Statements of Income and included in Other items, net, in the Condensed Consolidated Statements of Cash Flows.

Summary of the fair values of other financial instruments

Cash equivalents

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

Borrowings

We estimated the fair values of our borrowings by using Level 2 inputs. As of September 30, 2019 and December 31, 2018, the aggregate fair values of our borrowings were $33.3 billion and $35.0 billion, respectively, and the carrying values were $29.8 billion and $33.9 billion, respectively.

13. Derivative instruments

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

Cash flow hedges

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

As of September 30, 2019 and December 31, 2018, we had outstanding foreign currency forward contracts with aggregate notional amounts of $4.6 billion and $4.5 billion, respectively. As of December 31, 2018, we had outstanding foreign currency option contracts with an aggregate notional amount of $21 million and no such outstanding contracts as of September 30, 2019. We have designated these foreign currency forward and foreign currency option contracts, which are primarily euro based, as cash flow hedges. Accordingly, we report the unrealized gains and losses on these contracts in AOCI in the Condensed Consolidated Balance Sheets, and we reclassify them to Product sales in the Condensed Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

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

The notional amounts and interest rates of our cross-currency swaps as of September 30, 2019, were as follows (notional amounts in millions):

	Foreign currency			U.S. dollars		
Hedged notes	**Notional amounts**		**Interest rates**	**Notional amounts**		**Interest rates**
1.25% 2022 euro Notes	€	1,250	1.3%	$	1,388	3.2%
0.41% 2023 Swiss franc Bonds	CHF	700	0.4%	$	704	3.4%
2.00% 2026 euro Notes	€	750	2.0%	$	833	3.9%
5.50% 2026 pound sterling Notes	£	475	5.5%	$	747	6.0%
4.00% 2029 pound sterling Notes	£	700	4.0%	$	1,111	4.5%

During the three months ended September 30, 2019, our 2.125% 2019 euro Notes matured, and the related cross-currency swaps were settled.

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Condensed Consolidated Balance Sheets and are amortized into Interest expense, net, in the Condensed Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the nine months ended September 30, 2019, and amounts expected to be recognized during the subsequent 12 months are not material.

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

	Three months ended September 30,		Nine months ended September 30,	
Derivatives in cash flow hedging relationships	**2019**	**2018**	**2019**	**2018**
Foreign currency contracts	$ 176	$ 41	$ 245	$ 233
Cross-currency swap contracts	(105)	(22)	(240)	(99)
Total unrealized gains	$ 71	$ 19	$ 5	$ 134

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified for and were designated as fair value hedges. These interest rate swap contracts effectively convert fixed-rate coupons to floating-rate LIBOR-based coupons over the terms of the related hedge contracts. As of September 30, 2019 and December 31, 2018, we had interest rate swap contracts with aggregate notional amounts of $9.55 billion and $10.95 billion, respectively, that hedge certain portions of our long-term debt issuances.

For interest rate swap contracts that qualify for and are designated as fair value hedges, we recognize in Interest expense, net, in the Condensed Consolidated Statements of Income the unrealized gain or loss on the derivative resulting from the change in fair value during the period, as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. If a hedging relationship involving an interest rate swap contract is terminated, the gain or loss realized on contract termination is recorded as an adjustment to the carrying value of the debt and amortized into Interest expense, net, over the remaining life of the previously hedged debt.

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

	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
Condensed Consolidated Balance Sheets locations	**September 30, 2019**	**December 31, 2018**	**September 30, 2019**	**December 31, 2018**
Current portion of long-term debt	$ —	$ 2,396	$ —	$ (3)
Long-term debt	$ 9,811	$ 9,361	$ 391	$ (50)

(1) Current portion of long-term debt includes $1.0 billion of carrying value with discontinued hedging relationships as of December 31, 2018. Long-term debt includes $136 million and $137 million of carrying value with discontinued hedging relationships as of September 30, 2019 and December 31, 2018, respectively.

(2) Current portion of long-term debt includes $3 million of hedging adjustments on discontinued hedging relationships as of December 31, 2018. Long-term debt includes $36 million and $37 million of hedging adjustments on discontinued hedging relationships as of September 30, 2019 and December 31, 2018, respectively.

Impact of hedging transactions

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

	Three months ended September 30, 2019			Nine months ended September 30, 2019		
	Product sales	Interest and other income, net	Interest (expense), net	Product sales	Interest and other income, net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Condensed Consolidated Statements of Income	$ 5,463	$ 114	$ (313)	$ 16,323	$ 517	$ (988)
The effects of cash flow and fair value hedging:						
Gains (losses) on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency contracts	$ 26	$ —	$ —	$ 62	$ —	$ —
Cross-currency swap contracts	$ —	$ (64)	$ —	$ —	$ (92)	$ —
(Losses) gains on fair value hedging relationships—interest rate swap agreements:						
Hedged items[1]	$ —	$ —	$ (96)	$ —	$ —	$ (444)
Derivatives designated as hedging instruments	$ —	$ —	$ 96	$ —	$ —	$ 447

	Three months ended September 30, 2018			Nine months ended September 30, 2018		
	Product sales	Interest and other income, net	Interest (expense), net	Product sales	Interest and other income, net	Interest (expense), net
Total amounts recorded in income and (expense) line items presented in the Condensed Consolidated Statements of Income	$ 5,510	$ 126	$ (355)	$ 16,532	$ 519	$ (1,040)
The effects of cash flow and fair value hedging:						
Gains (losses) on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency contracts	$ 3	$ —	$ —	$ (51)	$ —	$ —
Cross-currency swap contracts	$ —	$ (36)	$ —	$ —	$ (170)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:						
Hedged items[1]	$ —	$ —	$ 48	$ —	$ —	$ 278
Derivatives designated as hedging instruments	$ —	$ —	$ (44)	$ —	$ —	$ (259)

[1] Gains (losses) on hedged items do not completely offset (losses) gains on the related designated hedging instruments due to amortization of the cumulative amounts of fair value hedging adjustments included in the carrying amount of the hedged debt for discontinued hedging relationships.

No portions of our cash flow hedge contracts were excluded from the assessment of hedge effectiveness. As of September 30, 2019, we expected to reclassify $97 million of net gains on our foreign currency and cross-currency swap contracts out of AOCI and into earnings during the next 12 months.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations in certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. Most of these exposures are hedged on a month-to-month basis. As of September 30, 2019 and December 31, 2018, the total notional amounts of these foreign currency forward contracts were $857 million and $737 million, respectively. Gains and losses recognized in earnings for our derivative instruments not designated as hedging instruments were not material for the three and nine months ended September 30, 2019 and 2018.

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

	Derivative assets		Derivative liabilities	
September 30, 2019	**Condensed Consolidated Balance Sheets locations**	**Fair values**	**Condensed Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 339	Accrued liabilities/ Other noncurrent liabilities	$ 6
Cross-currency swap contracts	Other current assets/ Other assets	12	Accrued liabilities/ Other noncurrent liabilities	478
Interest rate swap contracts	Other current assets/ Other assets	354	Accrued liabilities/ Other noncurrent liabilities	—
Total derivatives designated as hedging instruments		705		484
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	—	Accrued liabilities	—
Total derivatives not designated as hedging instruments		—		—
Total derivatives		$ 705		$ 484

	Derivative assets		Derivative liabilities	
December 31, 2018	**Condensed Consolidated Balance Sheets locations**	**Fair values**	**Condensed Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 181	Accrued liabilities/ Other noncurrent liabilities	$ 26
Cross-currency swap contracts	Other current assets/ Other assets	170	Accrued liabilities/ Other noncurrent liabilities	401
Interest rate swap contracts	Other current assets/ Other assets	56	Accrued liabilities/ Other noncurrent liabilities	149
Total derivatives designated as hedging instruments		407		576
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	1	Accrued liabilities	—
Total derivatives not designated as hedging instruments		1		—
Total derivatives		$ 408		$ 576

Our derivative contracts that were in liability positions as ofSeptember 30, 2019, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right but not the obligation to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the contracts may be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

The cash flow effects of our derivative contracts in the Condensed Consolidated Statements of Cash Flows are included in Net cash provided by operating activities, except for the settlement of notional amounts of cross-currency swaps, which are included in Net cash used in financing activities.

14. 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, 2018, Part I, Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations.* We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote; in Note 20, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018; or in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019.

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

Our legal proceedings involve various aspects of our business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing; in Note 20, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018; or in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019, in which we could incur a liability, our opponents seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process, which, in complex proceedings of the sort we face often extend for several years. As a result, none of the matters described in this filing; in Note 20, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018; or in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019, in which we could incur a liability, have progressed sufficiently through discovery and/or the development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

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

Novartis Breach of Contract Action

On September 17, 2019 and October 8, 2019, Novartis Pharma AG and Amgen, respectively, each filed its motion for judgment on the pleadings.

Sensipar® (cinacalcet) Litigation

Cipla Ltd. v. Amgen Inc.

On October 15, 2019, Amgen moved to dismiss Cipla Limited and Cipla USA, Inc.'s (collectively, Cipla) antitrust and fraud claims brought in the U.S. District Court for the District of Delaware (the Delaware District Court) for lack of standing and failure to state a claim.

Abbreviated New Drug Application (ANDA) Patent Litigation

Amgen Inc. v. Amneal Pharmaceuticals LLC, et al. Consolidated Case

As previously disclosed, (i) Amgen appealed the Delaware District Court's judgment of noninfringement of Amgen's U.S. Patent No. 9,375,405 (the '405 Patent) in favor of Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal), and Piramal Healthcare UK Limited (Piramal), and (ii) Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, Zydus) appealed the Delaware District Court's judgment of infringement by Zydus of Amgen's '405 Patent. On October 1, 2019, oral arguments for these appeals were held before the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court).

- v. Cipla, et al.

As previously disclosed, Amgen filed a motion requesting the Federal Circuit Court to vacate the Delaware District Court's judgment of noninfringement of Amgen's '405 Patent with respect to Watson Laboratories, Inc. and Actavis Pharma, Inc. Cipla filed an opposition to this motion and moved to participate in the appeal as either an intervenor or as *amicus curiae*. On September 13, 2019, the Federal Circuit Court denied Amgen's motion, lifted the stay of the briefing schedule which had been stayed pending disposition of Amgen's motion to vacate, and granted Cipla permission to file a brief as *amicus curiae*.

- v. Sun Pharmaceutical Industries Ltd., et al.

On September 18, 2019, the Delaware District Court denied the motion filed by Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, Sun), rejecting Sun's contention that its settlement agreement with Amgen permitted Sun's generic cinacalcet to enter the market without liability.

Amgen Inc. v. The ACME Laboratories Ltd.

On September 11, 2019, Amgen filed a lawsuit in the Delaware District Court against The ACME Laboratories Ltd. for infringement of Amgen's '405 Patent.

Amgen Inc. v. Accord Healthcare, Inc.

On October 21, 2019, based on a joint request of the parties, the Delaware District Court entered judgment of infringement and validity of Amgen's '405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, or importation into the United States of Accord Healthcare, Inc.'s cinacalcet product during the term of the '405 Patent unless specifically authorized pursuant to the confidential settlement agreement.

Sensipar® Antitrust Class Actions

On July 31, 2019, the multidistrict litigation panel entered an order consolidating in the Delaware District Court thefour class action lawsuits brought by plaintiffs on behalf of a putative class of direct or indirect purchasers of Sensipar® against Amgen and various entities affiliated with Teva Pharmaceutical Industries Ltd. On September 13, 2019, the plaintiffs filed amended complaints, and on October 15, 2019, Amgen filed its motion to dismiss both the direct purchaser plaintiffs' consolidated class action complaint and the indirect purchaser end payor plaintiffs' complaint.

Repatha® (evolocumab) Patent Litigation

Amgen Inc., et al. v. Sanofi, et al.

On August 28, 2019, the Delaware District Court ruled on the post-trial motions by Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC (formerly doing business as Aventis Pharmaceuticals Inc.) and Regeneron Pharmaceuticals, Inc., denying their request for a new trial and their request to reverse the jury verdict that U.S. Patent Nos. 8,829,165 (the '165 Patent) and 8,859,741 (the '741 Patent) provide written description support for the claimed inventions. The Delaware District Court also ruled as a matter of law that claims 19 and 29 of the '165 Patent and claim 7 of the '741 Patent are invalid for failing to meet the enablement requirement, overturning the jury verdict. On October 23, 2019, Amgen filed a notice of appeal to the Federal Circuit Court.

Patent Disputes in the International Region

The European Patent Office's decision on November 30, 2018 confirming the validity of Amgen's European Patent No. 2,215,124 has been appealed to the Technical Board of Appeal and a two-day hearing is scheduled to begin on March 24, 2020.

We are also involved in and expect future involvement in additional disputes regarding our proprotein convertase subtilisin/kexin type 9 (PCSK9) patents in other jurisdictions and regions, including matters filed against us and that we have filed in the United Kingdom, Germany, France and Japan.

ENBREL (etanercept) Patent Litigation

Immunex Corporation, et al. v. Samsung Bioepis Co., Ltd.

On August 5, 2019, defendant Samsung Bioepis Co., Ltd. responded to the complaint by Immunex Corporation (Immunex, a wholly-owned subsidiary of Amgen Inc.), Amgen Manufacturing, Limited (AML) and Hoffmann-La Roche Inc., denying infringement and seeking judgment that the patents-in-suit are invalid, unenforceable, and/or not infringed.

Immunex Corporation, et al. v. Sandoz Inc., et al.

On August 9, 2019, the U.S. District Court for the District of New Jersey (the New Jersey District Court) issued its decision upholding the validity of U.S. Patent Nos. 8,063,182 and 8,163,522. On October 8, 2019, by stipulation of Immunex and AML, and Sandoz Inc., Sandoz International GmbH and Sandoz GmbH (collectively, Sandoz), the New Jersey District Court entered final judgment and a permanent injunction prohibiting Sandoz from making, using, importing, selling or offering for sale Sandoz's etanercept product, and, on the same day, Sandoz appealed the final judgment to the Federal Circuit Court.

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

Amgen Inc., et al. v. Apotex Inc., et al.

On August 27, 2019, the U.S. District Court for the Southern District of Florida granted an unopposed motion to substitute Accord BioPharma in place of defendants Apotex Inc. and Apotex Corp.

In a separate challenge at the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (PTAB), on October 4, 2019, the PTAB granted judgment adverse to Apotex Biologics, LLC, Apotex Inc., and Apotex Corp. in post-grant review proceeding on Amgen's U.S. Patent No. 9,856,287 (the '287 Patent). The review proceedings continue with Kashiv Biosciences, LLC (Kashiv) as the sole petitioner.

Amgen Inc., et al. v. Kashiv Biosciences, LLC, et al.

On September 16, 2019, the New Jersey District Court entered Amgen and Kashiv's stipulation to dismiss without prejudice the causes of action directed solely to U.S. Patent No. 8,952,138 (the '138 Patent), in light of the PTAB's May 20, 2019 amended final written decision finding that claim 18 of the '138 Patent was obvious.

In a separate challenge by Kashiv at the PTAB, on September 11, 2019, the PTAB instituted the *inter partes* review (IPR) of Amgen's U.S. Patent Nos. 8,940,878 and 9,643,997 (the '997 Patent).

Amgen Inc., et al. v. Mylan Inc., et al.

The District Court for the Western District of Pennsylvania entered judgment of noninfringement of Amgen's U.S. Patent No. 8,273,707 and the '997 Patent on August 21, 2019, and September 17, 2019, respectively, based on a joint request of Amgen and Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V., resolving the patent disputes that had been the subject of the lawsuit.

Amgen Inc., et al. v. Sandoz Inc., et al.

On September 3, 2019, the Federal Circuit Court denied Amgen's petition for rehearing *en banc* in the consolidated appeal and reissued its opinion with amendment, but without disturbing its affirmance of grant of summary judgment of noninfringement in favor of Sandoz by the U.S. District Court for the Northern District of California.

Amgen Inc., et al. v. Tanvex BioPharma USA, Inc., et al.

On September 23, 2019, defendants Tanvex BioPharma USA, Inc., Tanvex BioPharma, Inc., and Tanvex Biologics Corporation responded to Amgen's complaint, denying infringement and seeking judgment of noninfringement and invalidity of Amgen's '287 Patent.

Fresenius PTAB Challenge

On October 16, 2019, the PTAB denied the petition by Fresenius Kabi USA, LLC and Fresenius Kabi SwissBiosim GmbH to institute the IPR with respect to the patentability of Amgen's '287 Patent.

Hospira EPOGEN® (epoetin alfa) Patent Litigation

Amgen Inc., et al. v. Hospira, Inc.

On September 30, 2019, the Federal Circuit Court heard argument on the appeal by Hospira, Inc. (Hospira), a subsidiary of Pfizer, and the cross-appeal by Amgen and AML, of the Delaware District Court's final judgment that Amgen's U.S. Patent No. 5,856,298 is valid and infringed by Hospira, that Amgen's U.S. Patent No. 5,756,349 is not infringed by Hospira, and awarding Amgen $70 million in damages for Hospira's infringement.

Litigation relating to our Biosimilar Products

KANJINTI™ (trastuzumab-anns) Patent Litigation*

Genentech, Inc. v. Amgen Inc.

As previously disclosed, Genentech, Inc. (Genentech) appealed the Delaware District Court's denial of Genentech's motion for a preliminary injunction and requested the Federal Circuit Court to enter an injunction prohibiting Amgen from continuing with its launch of KANJINTI™ until final resolution of the appeal. On August 7, 2019, the Federal Circuit Court denied Genentech's motion for an injunction pending appeal.

On September 4, 2019, Genentech filed its third amended complaint adding a demand for a jury trial and an award of damages for infringement. On September 23, 2019, the Delaware District Court ordered a stipulated dismissal with prejudice of all claims for infringement of certain asserted patents, leaving four patents asserted by Genentech in the litigation. On September 24, 2019, Amgen filed its answer to Genentech's third amended complaint denying infringement of any valid patent claim. On September 26, 2019, the Delaware District Court ordered that a 5-day jury trial on the patent issues commence on December 9, 2019, and the trial on damages (and therefore willfulness) be tried separately at a later date, if necessary.

MVASI™ (bevacizumab-awwb) Patent Litigation

Genentech, Inc. and City of Hope v. Immunex Rhode Island Corp. and Amgen Inc.

On August 16, 2019, the Federal Circuit Court denied Genentech's motion requesting the Federal Circuit Court enter an injunction prohibiting Amgen from marketing MVASI™ until final resolution of Genentech's appeal.

Genentech, Inc. and City of Hope v. Amgen Inc.

On August 22, 2019 and October 29, 2019, by stipulation of the parties, the Delaware District Court entered judgment of noninfringement, in each instance, with respect to one of the patents asserted in the consolidated lawsuit, leaving a total of six remaining patents asserted by Genentech in the litigation.

Humira® Biosimilar Antitrust Class Actions

As previously disclosed, twelve purported class actions against Amgen, along with AbbVie Inc. and AbbVie Biotechnology Ltd. were filed in the U.S. District Court for the Northern District of Illinois (the Illinois Northern District Court). On August 9, 2019, the plaintiffs filed their consolidated complaint in the Illinois Northern District Court. On October 11, 2019, the defendants filed a joint motion to dismiss the consolidated complaint (as well as brief individual motions), challenging the legal sufficiency of the plaintiffs' allegations to state any claim for relief under the law. No argument date has been set and plaintiffs' response to the motions is due on November 19, 2019.

* Registered in the U.S.

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, 2018, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019. 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 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, written statements or our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Such words as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume" and "continue" 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 forecasted by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, EPS, liquidity and capital resources, trends, planned dividends, stock repurchases and restructuring plans. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

Amgen is a highly focused biotechnology company committed to unlocking the potential of biology for patients suffering from serious illness. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Our principal products—those with the most significant annual commercial sales—are ENBREL, Neulasta®, Prolia®, XGEVA®, Aranesp®, KYPROLIS®, EPOGEN® and Sensipar®/Mimpara®. We also market a number of other products, including Nplate® (romiplostim), Vectibix® (panitumumab), Repatha®, Parsabiv® (etelcalcetide), BLINCYTO® (blinatumomab), Aimovig® (erenumab-aooe), NEUPOGEN®, AMGEVITA™ (adalimumab-atto), KANJINTI™, EVENITY® (romosozumab-aqqg), IMLYGIC® (talimogene laherparepvec), MVASI™ and Corlanor® (ivabradine).

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, 2019. 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, 2018, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019.

Products/Pipeline

Oncology/Hematology

KYPROLIS®

- In September 2019, we announced that the phase 3 CANDOR (Carfilzomib, Daratumumab and Dexamethasone for Patients With Relapsed and/or Refractory Multiple Myeloma) study evaluating KYPROLIS® in combination with dexamethasone and DARZALEX® (daratumumab) compared to KYPROLIS® and dexamethasone alone met its primary endpoint of progression-free survival.

Inflammation

ENBREL

- In August 2019, we announced that the U.S. District Court for the District of New Jersey ruled in Amgen's favor on validity of the two patents that describe and claim ENBREL and methods for making it. See Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended September 30, 2019.

Bone health

EVENITY®

- In October 2019, we and UCB announced that the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) has adopted a positive opinion recommending Marketing Authorization for EVENITY® for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture and with no history of myocardial infarction or stroke.

Biosimilars

ABP 798 (biosimilar rituximab)

- In August 2019, we and Allergan plc announced positive top-line results from a comparative clinical study evaluating the efficacy and safety of ABP 798, a biosimilar candidate to Rituxan® (rituximab), compared to Rituxan® in patients with CD20-positive B-cell non-Hodgkin's lymphoma. The primary endpoint, an assessment of overall response rate by week 28, was within the prespecified margin for ABP 798 compared to Rituxan®, showing clinical equivalence. Safety and immunogenicity of ABP 798 were comparable to Rituxan®.

Acquisition

- In August 2019, we announced that we had entered into an agreement with Celgene in connection with Celgene's previously announced merger with BMS to acquire worldwide rights to Otezla®, the only oral, nonbiologic treatment for psoriasis and psoriatic arthritis, and certain related assets and liabilities for $13.4 billion in cash. The transaction is expected to close by the end of 2019.

Selected financial information

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

	Three months ended September 30,			Nine months ended September 30,		
	2019	2018	Change	2019	2018	Change
Product sales						
U.S.	$ 4,029	$ 4,260	(5)%	$ 12,162	$ 12,774	(5)%
ROW	1,434	1,250	15 %	4,161	3,758	11 %
Total product sales	5,463	5,510	(1)%	16,323	16,532	(1)%
Other revenues	274	394	(30)%	842	985	(15)%
Total revenues	$ 5,737	$ 5,904	(3)%	$ 17,165	$ 17,517	(2)%
Operating expenses	$ 3,261	$ 3,581	(9)%	$ 9,539	$ 9,636	(1)%
Operating income	$ 2,476	$ 2,323	7 %	$ 7,626	$ 7,881	(3)%
Net income	$ 1,968	$ 1,859	6 %	$ 6,139	$ 6,466	(5)%
Diluted EPS	$ 3.27	$ 2.86	14 %	$ 10.01	$ 9.61	4 %
Diluted shares	602	649	(7)%	613	673	(9)%

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

Total product sales decreased for the three and nine months ended September 30, 2019, driven primarily by a decline in net selling price, offset partially by higher unit demand. For the remainder of 2019, we continue to expect a lower net selling price compared with 2018.

Other revenues decreased for the three and nine months ended September 30, 2019, driven primarily by lower milestone payments, offset partially by higher royalties.

Operating expenses decreased for the three and nine months ended September 30, 2019 and 2018, driven primarily by the favorable change resulting from an impairment charge associated with a nonkey IPR&D asset in the third quarter of 2018. The decrease in the nine months ended September 30, 2019, was offset partially by increased R&D expenses.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is offset partially by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material for the three and nine months ended September 30, 2019 and 2018.

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,		
	2019	2018	Change	2019	2018	Change
ENBREL	$ 1,366	$ 1,292	6 %	$ 3,880	$ 3,699	5 %
Neulasta®	711	1,051	(32)%	2,556	3,306	(23)%
Prolia®	630	532	18 %	1,920	1,636	17 %
XGEVA®	476	433	10 %	1,446	1,330	9 %
Aranesp®	452	477	(5)%	1,302	1,403	(7)%
KYPROLIS®	266	232	15 %	778	717	9 %
EPOGEN®	215	252	(15)%	657	746	(12)%
Sensipar®/Mimpara®	109	409	(73)%	444	1,326	(67)%
Other products	1,238	832	49 %	3,340	2,369	41 %
Total product sales	$ 5,463	$ 5,510	(1)%	$ 16,323	$ 16,532	(1)%

Future sales of our products will depend in part on the factors discussed below and in the following sections of our Annual Report on Form 10-K for the year ended December 31, 2018: (i) Item 1. Business—Marketing, Distribution and Selected Marketed Products, (ii) Item 1A. Risk Factors and (iii) Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview, and Results of Operations—Product Sales, as well as in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019, in (i) Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Product Sales, and (ii) Part II, Item 1A. Risk Factors.

ENBREL

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

	Three months ended September 30,			Nine months ended September 30,		
	2019	2018	Change	2019	2018	Change
ENBREL — U.S.	$ 1,323	$ 1,242	7 %	$ 3,744	$ 3,544	6 %
ENBREL — Canada	43	50	(14)%	136	155	(12)%
Total ENBREL	$ 1,366	$ 1,292	6 %	$ 3,880	$ 3,699	5 %

The increase in ENBREL sales for the three months ended September 30, 2019, was driven primarily by an increase in net selling price and favorable impacts from changes in accounting estimates of sales deductions, offset partially by lower unit demand. The increase in ENBREL sales for the nine months ended September 30, 2019, was driven primarily by favorable impacts from changes in accounting estimates of sales deductions and an increase in net selling price, offset partially by lower unit demand and unfavorable changes in inventory. In 2019, we continue to expect lower unit demand compared with 2018.

In April 2019, the U.S. Food and Drug Administration (FDA) approved a second biosimilar version of ENBREL, and we are involved in patent litigations with the two companies seeking to market their FDA-approved biosimilar versions of ENBREL. See Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended September 30, 2019; Note 20, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018; and Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2019. Other companies are also developing purposed biosimilar versions of ENBREL. Companies with approved biosimilar versions of ENBREL may seek to enter the U.S. market if we are not successful in our litigations, or even earlier.

Neulasta®

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

	Three months ended September 30,			Nine months ended September 30,		
	2019	2018	Change	2019	2018	Change
Neulasta®— U.S.	$ 619	$ 897	(31)%	$ 2,231	$ 2,854	(22)%
Neulasta®— ROW	92	154	(40)%	325	452	(28)%
Total Neulasta®	$ 711	$ 1,051	(32)%	$ 2,556	$ 3,306	(23)%

The decreases in global Neulasta® sales for the three and nine months ended September 30, 2019, were driven by the impact of biosimilar competition on net selling price and unit demand. Neulasta® sales included a $98 million order from the U.S. government in the first quarter of 2019.

Biosimilar versions of Neulasta® have been approved and launched, and other biosimilar versions may also receive approval in the near future. Therefore, we face increased competition in the United States and Europe, which has had and will continue to have a material adverse impact on sales of Neulasta®. For a discussion of ongoing patent litigations related to these and other biosimilars, see Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended September 30, 2019; Note 20, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018; and Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019.

Prolia®

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

	Three months ended September 30,			Nine months ended September 30,		
	2019	2018	Change	2019	2018	Change
Prolia® — U.S.	$ 425	$ 354	20%	$ 1,273	$ 1,070	19%
Prolia® — ROW	205	178	15%	647	566	14%
Total Prolia®	$ 630	$ 532	18%	$ 1,920	$ 1,636	17%

The increases in global Prolia® sales for the three and nine months ended September 30, 2019, were driven by higher unit demand. Prolia®, which has a six-month dosing interval, has exhibited a historical sales pattern, with the first and third quarters of a year representing lower sales than the second and fourth quarters of a year.

XGEVA®

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

	Three months ended September 30,			Nine months ended September 30,		
	2019	2018	Change	2019	2018	Change
XGEVA® — U.S.	$ 356	$ 323	10%	$ 1,091	$ 994	10%
XGEVA® — ROW	120	110	9%	355	336	6%
Total XGEVA®	$ 476	$ 433	10%	$ 1,446	$ 1,330	9%

The increases in global XGEVA® sales for the three and nine months ended September 30, 2019, were driven primarily by higher unit demand.

Aranesp®

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

	Three months ended September 30,			Nine months ended September 30,		
	2019	2018	Change	2019	2018	Change
Aranesp® — U.S.	$ 204	$ 248	(18)%	$ 578	$ 714	(19)%
Aranesp® — ROW	248	229	8 %	724	689	5 %
Total Aranesp®	$ 452	$ 477	(5)%	$ 1,302	$ 1,403	(7)%

The decreases in global Aranesp® sales for the three and nine months ended September 30, 2019, were driven primarily by the impact of competition on unit demand in the United States.

Aranesp® faces competition from a long-acting erythropoiesis-stimulating agent. Aranesp® also faces competition from a biosimilar version of EPOGEN®. Other biosimilar versions of EPOGEN® may also receive approval in the future. In 2019, sales in the United States have declined, and we expect them to continue to decline at a faster rate than in 2018 due to short- and long-acting competition.

KYPROLIS®

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

	Three months ended September 30, 2019			Nine months ended September 30,		
	2019	2018	Change	2019	2018	Change
KYPROLIS® — U.S.	$ 163	$ 142	15%	$ 483	$ 430	12%
KYPROLIS® — ROW	103	90	14%	295	287	3%
Total KYPROLIS®	$ 266	$ 232	15%	$ 778	$ 717	9%

The increases in global KYPROLIS® sales for the three and nine months ended September 30, 2019, were driven primarily by higher unit demand.

We are engaged in litigation with two related companies that are challenging our material patents related to KYPROLIS® and are seeking to market generic carfilzomib products. Under the Hatch-Waxman Act, FDA approval of the ANDA at issue is stayed until at least January 20, 2020 (although the stay may be lifted in connection with a court order or in certain other instances permitted under the statute). Separately, we have entered into confidential settlement agreements with other companies developing generic carfilzomib products, and the court has entered consent judgments enjoining those companies from infringing certain of our patents, subject to terms of the confidential settlement agreements. See Note 20, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018, and Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019. The FDA has reported that it has tentatively approved ANDAs filed by two companies for generic carfilzomib products. The date of final approval of those ANDAs is governed by the Hatch-Waxman Act and any applicable settlement agreements between the parties.

EPOGEN®

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

	Three months ended September 30,			Nine months ended September 30,		
	2019	2018	Change	2019	2018	Change
EPOGEN® — U.S.	$ 215	$ 252	(15)%	$ 657	$ 746	(12)%

The decreases in EPOGEN® sales for the three and nine months ended September 30, 2019, were driven primarily by a decline in net selling price due to our contract with DaVita Inc. (DaVita). In 2019, we continue to expect a lower net selling price compared with 2018 due to our contract with DaVita.

A biosimilar version of EPOGEN® has been approved and launched, and other biosimilar versions may also receive approval in the future. Therefore, we face increased competition in the United States, which has had and will continue to have a material adverse impact on sales of EPOGEN®. For a discussion of ongoing patent litigation related to one of these biosimilars, see Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended September 30, 2019, and Note 20, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018.

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,		
	2019	2018	Change	2019	2018	Change
Sensipar® — U.S.	$ 38	$ 330	(88)%	$ 216	$ 1,069	(80)%
Sensipar®/Mimpara® — ROW	71	79	(10)%	228	257	(11)%
Total Sensipar®/Mimpara®	$ 109	$ 409	(73)%	$ 444	$ 1,326	(67)%

The decreases in global Sensipar®/Mimpara® sales for the three and nine months ended September 30, 2019, were driven by the impact of at-risk launches by generic competitors on unit demand.

Our U.S. composition-of-matter patent related to Sensipar®, a small molecule, expired in March 2018. We are involved in litigation with a number of companies seeking to market generic cinacalcet products surrounding our U.S. formulation patent, which expires in September 2026. Separately, we have entered into confidential settlement agreements with other companies developing generic cinacalcet products, and the court has entered consent judgments enjoining those companies from infringing certain of our patents, subject to terms of the confidential settlement agreements. See Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended September 30, 2019; Note 20, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018; and Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019. Certain companies manufacturing generics began selling their generic cinacalcet products in the United States in late 2018 and 2019, and some of this generic product remains commercially available in the United States from third-party distributors. Sensipar® sales have been and we believe may continue to be adversely impacted as a result of generic-product sales in the U.S. market.

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,		
	2019	2018	Change	2019	2018	Change
Nplate®— U.S.	$ 119	$ 107	11 %	$ 355	$ 326	9 %
Nplate®— ROW	76	70	9 %	230	209	10 %
Vectibix®— U.S.	79	71	11 %	236	214	10 %
Vectibix®— ROW	117	110	6 %	326	309	6 %
Repatha®— U.S.	85	72	18 %	259	254	2 %
Repatha®— ROW	83	48	73 %	202	137	47 %
Parsabiv® — U.S.	137	92	49 %	394	194	*
Parsabiv® — ROW	20	10	100 %	57	22	*
Biosimilars — U.S.	81	—	*	81	—	*
Biosimilars — ROW	92	19	*	229	21	*
BLINCYTO® — U.S.	47	33	42 %	126	97	30 %
BLINCYTO® — ROW	38	25	52 %	106	70	51 %
Aimovig® — U.S.	66	22	*	208	24	*
NEUPOGEN®— U.S.	32	52	(38)%	137	180	(24)%
NEUPOGEN®— ROW	22	33	(33)%	65	110	(41)%
EVENITY® — U.S.	12	—	*	15	—	*
EVENITY®— ROW	47	—	*	89	—	*
Other — U.S.	28	23	22 %	78	64	22 %
Other — ROW	57	45	27 %	147	138	7 %
Total other products	$ 1,238	$ 832	49 %	$ 3,340	$ 2,369	41 %
Total U.S. — other products	$ 686	$ 472	45 %	$ 1,889	$ 1,353	40 %
Total ROW — other products	552	360	53 %	1,451	1,016	43 %
Total other products	$ 1,238	$ 832	49 %	$ 3,340	$ 2,369	41 %

* Change in excess of 100%.

Operating expenses

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

	Three months ended September 30,			Nine months ended September 30,		
	2019	2018	Change	2019	2018	Change
Operating expenses:						
Cost of sales	$ 1,036	$ 1,037	— %	$ 3,103	$ 3,005	3 %
% of product sales	19.0%	18.8%		19.0%	18.2%	
% of total revenues	18.1%	17.6%		18.1%	17.2%	
Research and development	$ 1,001	$ 926	8 %	$ 2,804	$ 2,555	10 %
% of product sales	18.3%	16.8%		17.2%	15.5%	
% of total revenues	17.4%	15.7%		16.3%	14.6%	
Selling, general and administrative	$ 1,223	$ 1,293	(5)%	$ 3,637	$ 3,773	(4)%
% of product sales	22.4%	23.5%		22.3%	22.8%	
% of total revenues	21.3%	21.9%		21.2%	21.5%	
Other	$ 1	$ 325	(100)%	$ (5)	$ 303	*

* Change in excess of 100%.

Cost of sales

Cost of sales increased to 18.1% of total revenues for the three months ended September 30, 2019, driven primarily by unfavorable product mix, offset partially by lower manufacturing costs.

Cost of sales increased to 18.1% of total revenues for the nine months ended September 30, 2019, driven primarily by unfavorable product mix, offset partially by lower royalties and by the benefit of Hurricane Maria insurance proceeds. In 2019, product mix will continue to negatively impact cost of sales.

Research and development

The increases in R&D expense for the three and nine months ended September 30, 2019, were driven by increased spending in research and early pipeline in support of our oncology programs, offset partially by decreased spending in support of marketed products.

Selling, general and administrative

The decrease in Selling, general and administrative expenses for the three months ended September 30, 2019, was driven primarily by lower general and administrative expenses as well as the end of certain amortization of intangible assets in 2018.

The decrease in Selling, general and administrative expenses for the nine months ended September 30, 2019, was driven primarily by lower general and administrative expenses, the end of certain amortization of intangible assets in 2018 and lower marketed product support, offset partially by investments in launch products.

Other

Other operating expenses for the three and nine months ended September 30, 2019 and 2018, include changes in the fair values of contingent consideration liabilities related to business combinations. Other operating expenses included an impairment charge of $330 million associated with a nonkey IPR&D asset in the third quarter of 2018.

Nonoperating expense/income and income taxes

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Interest expense, net	$ 313	$ 355	$ 988	$ 1,040
Interest and other income, net	$ 114	$ 126	$ 517	$ 519
Provision for income taxes	$ 309	$ 235	$ 1,016	$ 894
Effective tax rate	13.6%	11.2%	14.2%	12.1%

Interest expense, net

The decreases in Interest expense, net, for the three andnine months ended September 30, 2019, were due primarily to a reduction in outstanding long-term debt as a result of maturities in the current year. The decrease in the year-to-date period was offset partially by higher average interest rates on variable-rate debt in the current year period compared with the prior year.

Interest and other income, net

The decreases in Interest and other income, net, for the three and nine months ended September 30, 2019, were due primarily to reduced interest income as a result of lower average cash balances and lower gains on our strategic equity investments, offset partially by reduced net losses on sales of investments in interest-bearing securities. In addition, the decrease for the nine-month period was further reduced by a gain recognized in connection with our acquisition of Kirin-Amgen, Inc., during the first quarter of 2018.

Income taxes

The increases in our effective tax rates for the three andnine months ended September 30, 2019, were due primarily to a prior-year tax benefit associated with intercompany sales under U.S. corporate tax reform.

As previously disclosed, we received an RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Final resolution of this complex matter is not likely within the next 12 months and could have a material impact on our condensed consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued.

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, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 20,853	$ 29,304
Total assets	$ 59,535	$ 66,416
Current portion of long-term debt	$ 2,049	$ 4,419
Long-term debt	$ 27,742	$ 29,510
Stockholders' equity	$ 10,927	$ 12,500

Cash, cash equivalents and marketable securities

We have global access to our $20.9 billion balance of cash, cash equivalents and marketable securities because we no longer reinvest the related undistributed foreign earnings indefinitely outside the United States. As a result of U.S. corporate tax reform in 2017, we recorded a repatriation tax liability on undistributed earnings generated from operations in foreign tax jurisdictions, which will be paid over eight years. The first two annual payments were made in April 2018 and April 2019, and the remaining scheduled payments total $6.2 billion. Further, the timing of settlement of the sales of certain of our securities reduced the balance of cash, cash equivalents and marketable securities as of September 30, 2019, as $1.1 billion of unsettled sales of securities were recorded in Other current assets in the Condensed Consolidated Balance Sheets. The change in composition of our portfolio to shorter duration investments during the third quarter of 2019 reflects our preparation to fund the cost of the anticipated acquisition of the worldwide rights to Otezla® (see Significant developments).

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

Capital allocation

Consistent with the objective to optimize our capital structure, we seek to deploy our accumulated cash balances in an efficient manner, and we consider several alternatives such as payment of dividends, stock repurchases, repayment of debt and strategic transactions that expand our portfolio of products in areas of therapeutic interest.

We intend to continue to invest in our business while returning capital to stockholders through the payment of cash dividends and stock repurchases, thereby 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, 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 the Company's agreements. In addition, the timing and amount of stock repurchases may also be affected by stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include private block purchases, tender offers and market transactions.

In August 2019, March 2019 and December 2018, the Board of Directors declared quarterly cash dividends of $1.45 per share of common stock, which were paid on September 6, 2019, June 7, 2019 and March 8, 2019, respectively, an increase of 10% over the quarterly cash dividend paid in each quarter of 2018. In October 2019, the Board of Directors declared a quarterly cash dividend of $1.45 per share of common stock, which will be paid on December 6, 2019.

We have also returned capital to stockholders through our stock repurchase program. During the nine months ended September 30, 2019, we repurchased $6.6 billion of common stock. In May 2019, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $5.0 billion. As of September 30, 2019, $3.6 billion of authorization remained available under our stock repurchase program.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of September 30, 2019 and December 31, 2018. Our accumulated deficit is not expected to affect our future ability to operate, repurchase stock, pay dividends or repay our debt given our continuing profitability and strong financial position.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt markets and equity markets. See our Annual Report on Form 10-K for the year ended December 31, 2018, Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business*.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which requires that we maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of September 30, 2019.

Cash flows

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

	Nine months ended September 30,	
	2019	**2018**
Net cash provided by operating activities	$ 6,636	$ 8,102
Net cash provided by investing activities	$ 11,672	$ 18,976
Net cash used in financing activities	$ (13,838)	$ (18,922)

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, 2019, decreased compared with the same period in the prior year due to lower Net income, adjusted for noncash items, timing of payments to corporate partners and sales deductions paid to customers.

Investing

Cash provided by investing activities during the nine months ended September 30, 2019 and 2018, was due primarily to net cash inflows related to marketable securities of $12.4 billion and $19.3 billion, respectively. Higher cash inflows in the prior year reflect the cash to fund a $10.0 billion tender offer completed in 2018 to repurchase our common stock. Capital expenditures during the nine months ended September 30, 2019 and 2018, were $430 million and $513 million, respectively. We currently estimate 2019 spending on capital projects to be approximately $650 million.

Financing

Cash used in financing activities during the nine months ended September 30, 2019, was due primarily to repurchases of our common stock of $6.6 billion, repayment of debt of $4.5 billion and payment of dividends of $2.6 billion. Cash used in financing activities during the nine months ended September 30, 2018, was due primarily to repurchases of our common stock of $15.7 billion, repayment of debt of $500 million and payment of dividends of $2.7 billion. See Note 10, Financing arrangements, and Note 11, Stockholders' equity, to the condensed consolidated financial statements for further discussion.

Critical accounting policies

The preparation of our condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2018. There were no material changes to our critical accounting policies during the nine months ended September 30, 2019.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Information about our market risk is disclosed in Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the year ended December 31, 2018, and is incorporated herein by reference. There have been no material changes during the nine months ended September 30, 2019, to the information provided in Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the year ended December 31, 2018.

Item 4. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under the Securities 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, 2019.

Management determined that, as of September 30, 2019, 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 14, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the period ended September 30, 2019, and Note 13, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019, for discussions that are limited to certain recent developments concerning our legal proceedings. Those discussions should be read in conjunction with Note 20, Contingencies and commitments, to the consolidated financial statements in Part IV of our Annual Report on Form 10-K for the year ended December 31, 2018.

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

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

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

—Changing federal coverage and reimbursement policies and practices have impacted and may continue to impact access to and sales of our products

A substantial portion of our U.S. business relies on reimbursement from U.S. federal government healthcare programs and commercial insurance plans regulated by the U.S. federal and state governments. See our Annual Report on Form 10-K for the year ended December 31, 2018, Part I, Item 1. Business—Reimbursement. Our business has and will continue to be impacted by legislative actions changing U.S. federal reimbursement policy. For example, in February 2018, the U.S. Congress passed legislation requiring biopharmaceutical manufacturers to provide greater discounts beginning in 2019 on products dispensed to patients in the coverage gap between the initial coverage limit of Medicare Part D and the program's catastrophic-coverage threshold, which has and will continue to reduce our net product sales relating to such patients. Additional legislative proposals have been introduced by members of Congress to overhaul provisions of the Patient Protection and Affordable Care Act to allow commercial-level reimportation of prescription medications from Canada or other countries and to enable Medicare to negotiate drug prices with biopharmaceutical manufacturers. Congressional focus on drug pricing has increased since the U.S. House of Representatives changed party control following the November 2018 election, and our industry is currently under greater scrutiny by Congress. For example, in January 2019, the chair of the House Oversight and Reform Committee sent letters to twelve different biopharmaceutical manufacturers, including Amgen, seeking documents and detailed information about such companies' drug pricing practices. A number of other Congressional committees have also held hearings and evaluated proposed legislation on drug pricing. For example, in July 2019, the bipartisan Senate Finance Committee advanced a bill that would, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries, and make a number of changes to how drugs are reimbursed in Medicare Part B. In September 2019, a new drug pricing bill, H.R. 3, was introduced in the House, which, if enacted, enables direct price negotiations by the federal government on certain drugs (with the maximum price paid by Medicare capped based on an international index) and requires manufacturers to offer these negotiated prices to other payers, and restricts manufacturers from raising prices on drugs covered by Medicare Parts B and D. We expect continued significant focus on health care and drug pricing legislation through the November 2020 U.S. presidential election and beyond.

Also, our business has been and is expected to continue to be impacted by changes in U.S. federal reimbursement policy resulting from executive actions, federal regulations, or federal demonstration projects. For example, the U.S. presidential administration's (the Administration) drug pricing "blueprint" released in May 2018 contains an array of policy ideas intended to increase competition, improve the negotiating power of the federal government, reduce drug prices and lower patient out-of-pocket costs with the potential to significantly impact, whether individually or collectively, the biopharmaceutical industry. Such policy ideas include moving coverage and reimbursement for Medicare Part B drugs into Medicare Part D, instituting a competitive acquisition program for Part B drugs in which competing third-party vendors take on the financial risk of acquiring drugs and billing Medicare, removing the safe harbor protection under the federal anti-kickback statute for drug rebates paid to payers, and requiring the inclusion of drug price information in direct-to-consumer drug advertising.

Since the release of this blueprint, the president and/or federal agencies, including the Centers for Medicare & Medicaid Services (CMS), have announced a number of demonstration projects, recommendations and proposals to implement various elements of the drug pricing blueprint. CMS is the federal agency responsible for administering Medicare and overseeing state Medicaid programs and Health Insurance Marketplaces, and has substantial power to implement policy changes or demonstration projects that can quickly and significantly affect how drugs, including our products, are covered and reimbursed. For example, in late 2018, CMS began evaluating a pilot program referred to as the "International Price Index (IPI)" model to, among other things, initially cover fifty percent of Medicare Part B single source drugs at payment amounts more closely aligned with international drug prices, and in June 2019, Administration officials announced that the Office of Management and Budget is reviewing a draft of a proposed rule to implement the IPI model. CMS has also issued guidance to allow certain Medicare plans offered by private insurance companies to require that patients receiving Medicare Part B drugs first try a drug preferred by the plan before covering another therapy (Step Therapy) and proposing lower reimbursement rates for new Part B drugs.

Separate from the drug pricing blueprint, CMS has undertaken other demonstration projects to test care models, such as the CMS Oncology Care Model, which provides participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare costs without negatively impacting the efficacy of care. We believe the Oncology Care Model has reduced utilization of certain of our oncology products by participating physician practices and expect it to continue to do so in the future. And in July 2019, CMS released a proposed rule creating a new mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants for end-stage renal disease patients that, if finalized as proposed, could result in changes to treatment of such patients, including reduction of the use of our erythropoiesis-stimulating agents and calcimimetic products. CMS has also solicited suggestions regarding other potential care models.

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

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products. Government price reporting regulations are complex and may require a manufacturer to update certain previously submitted 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.

—Changing reimbursement and pricing actions in various states may impact access to and have impacted and may continue to impact sales of our products

At the state level, government actions or ballot initiatives can also affect how our products are covered and reimbursed and/or create additional pressure on our pricing decisions. A number of states have adopted, and many other states have discussed and debated and are considering, new pricing actions, including proposals designed to require biopharmaceutical manufacturers to publicly report proprietary pricing information, limit price increases or to place a maximum price ceiling or cap on biopharmaceutical products. Existing and proposed state pricing laws have added complexity to the pricing of drugs and may already be impacting industry pricing decisions. For example, in October 2017, California enacted a drug-pricing transparency bill that requires biopharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. Oregon and Washington passed similar laws in 2019. Other states are seeking to change the way they pay for drugs for patients covered by state programs. For example, in August 2018 the Ohio Department of Medicaid ordered that all the state's Medicaid managed care plans terminate and renegotiate contracts with Pharmacy Benefit Managers (PBMs) to eliminate PBMs billing the state more than treatments that they reimburse pharmacists for Medicaid patient prescriptions. In January 2019, California's governor issued an executive order expanding state Medicaid coverage and directing its agencies and programs to consolidate drug purchases and to negotiate drug prices with manufacturers.

In addition, New York, Massachusetts, and Ohio have established Medicaid drug spending caps that require supplemental rebates for drugs that exceed specified spending thresholds. Additionally, some states, including Colorado, Florida, Maine and Vermont, have enacted laws, and several other states have proposed laws, to facilitate the importation of drugs from Canada. These state importation programs must first be approved by the U.S. Department of Health and Human Services under a federal statute that excludes biologics, but state and federal legislatures and agencies may seek ways to extend such measures to biologics. Other states could adopt similar approaches or could pursue different policy changes in a continuing effort to reduce their costs. Ultimately, as with U.S. federal government actions, existing or future state government actions or ballot initiatives may also have a material adverse effect on our product sales, business and results of operations.

—U.S. commercial payer actions have impacted and may continue to impact access to and sales of our products

Payers, including healthcare insurers, PBMs, integrated healthcare delivery systems and group purchasing organizations, increasingly seek ways to reduce their costs. With increasing frequency, payers are adopting benefit plan changes that shift a greater portion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient co-pay or coinsurance obligations and more significant limitations on patients' use of manufacturer commercial co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs). Payers have sought and have continued to seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage, particularly in treatment areas where the payer has taken the position that multiple branded products are therapeutically comparable. Payers also control costs by imposing restrictions on access to or usage of our products, such as Step Therapy or requiring that patients receive the payer's prior authorization before covering the product, or that patients use a mail-order pharmacy or a limited network of fully-owned specialty pharmacies; payers may also choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. For example, the burdensome administrative processes required for physicians to demonstrate or document that the patients for whom Repatha® has been prescribed meet payer utilization management criteria has limited and may continue to limit patient access to Repatha® treatment. In an effort to reduce barriers to access, we reduced the net price of Repatha® by providing greater discounts and rebates to payers, including PBMs that administer Medicare Part D prescription drug plans. However, affordability of patient out-of-pocket co-pay cost has and may continue to limit patient use. For example, a very high percentage of Medicare patients have abandoned their Repatha® prescriptions rather than pay their co-pay payment. In late 2018 and early 2019, we introduced a set of new National Drug Codes (NDCs) to make Repatha® available at a lower list price to attempt to address affordability for patients, particularly those on Medicare. To allow payers time to make a smooth transition to the lower list price and avoid incentivizing PBMs to immediately switch patients to the other available PCSK9 inhibitor that offered them a higher overall rebate due to its higher list price, we also continued to offer Repatha® at the original list price for a period of time. Despite these net and list price reductions, some payers have and may continue to restrict patient access, change formulary coverage for Repatha®, seek further discounts or rebates or take other actions that could reduce our sales of Repatha®. Further, in the competitive PCSK9 inhibitor marketplace, many payers have not yet adopted the new NDCs we introduced for lower-list price Repatha®, including a number of PBMs that continue to cover Repatha® at the original list price in part because of the higher rebates they receive for it. These factors have and may continue to limit patient affordability and use and to negatively impact our sales of Repatha®.

Further, significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. For example, in the United States, in 2018, the top three PBMs oversaw greater than two-thirds of prescription claims as well as government and commercial covered lives. The consolidation among insurers, PBMs and other payers, including through integrated healthcare delivery systems and/or with specialty or mail-order pharmacies and pharmacy retailers, has increased the negotiating leverage such entities have over us and other drug manufacturers and has resulted in greater price discounts, rebates and fees for other services being realized by those payers. For example, during the fourth quarter of 2018, two of the nation's largest PBMs, Express Scripts and CVS Health, completed their combinations with major insurance companies Cigna and Aetna, respectively. Additional consolidation would further increase the leverage of such entities. Ultimately, additional discounts, rebates, coverage or plan changes, restrictions or exclusions imposed by these commercial payers could have a material adverse effect on our product sales, business and results of operations.

—Government and commercial payer actions outside the United States have impacted and will continue to impact access to and sales of our products

Outside the United States, we expect countries will continue to take actions to reduce their drug expenditures. See our Annual Report on Form 10-K for the year ended December 31, 2018, Part I, Item 1. Business—Reimbursement. International reference pricing (IRP) has been widely used by many countries outside the United States to control costs based on an external benchmark of a product's price in other countries. IRP policies can quickly and frequently change and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. In addition, countries may refuse to reimburse or may restrict the reimbursed population for a product when their national health technology assessments do not consider a medicine to demonstrate sufficient clinical benefit beyond existing therapies or that it does not meet certain cost

effectiveness thresholds. For example, despite the EMA's May 2018 approval of Repatha® for the treatment of patients with established atherosclerotic disease, reimbursement for Repatha® in France and Germany has remained limited to narrower patient populations (such as those with homozygous familial hypercholesterolemia) following national health technology assessments in mid-2018. Some countries decide on reimbursement between potentially competing products through national or regional tenders that often result in one product receiving most or all of the sales in that country or region. Failure to obtain coverage and reimbursement for our products, a deterioration in their existing coverage and reimbursement, or a decline in the timeliness or certainty of payment by payers to physicians and other providers has impacted and may further negatively impact the ability or willingness of healthcare providers to prescribe our products for their patients and otherwise negatively affect the use of our products or the prices we receive for them. Such changes can and have had a material adverse effect on our product sales, business and results of operations.

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

We seek innovation through significant investment in both internal R&D and external transactions including collaborations, partnering, alliances, licenses, joint ventures, mergers and acquisitions (acquisition activity). We have an ongoing process of evaluating such potential acquisition activity opportunities that we expect will contribute to our future growth and expand our geographic footprint, product offerings and/or our R&D pipeline. For example, in late August 2019, we announced that we entered into an agreement with Celgene to acquire worldwide rights to Otezla® and certain related assets and liabilities (see Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Significant developments).

Acquisition activities may be subject to regulatory approvals or other requirements that are not within our control. For example, the merger between BMS and Celgene, including the required divestiture of Otezla®, is contingent upon and subject to approval by the Federal Trade Commission (FTC) via a divestiture order. Our role as the acquirer of Otezla® pursuant to that order is also subject to FTC approval. There can be no assurance that such regulatory or other approvals will be obtained or that all closing conditions required in connection with the Otezla® acquisition will be satisfied or waived, which could result in us being unable to complete the planned acquisition.

Acquisition activities are complex, time consuming and expensive, and may result in unanticipated costs, delays or other operational or financial problems related to integrating the acquired company and business with our company, which may divert our management's attention from other business issues and opportunities and restrict the full realization of the anticipated benefits of such transactions within the expected timeframe or at all. We may pay substantial amounts of cash, incur debt or issue equity securities to pay for acquisition activities, which could adversely affect our liquidity or result in dilution to our stockholders, respectively. Further, failures or difficulties in integrating or retaining new personnel or in integrating the operations of the businesses, products or assets we acquire (including related technology, commercial operations, compliance programs, manufacturing, distribution and general business operations and procedures) may affect our ability to realize the benefits of the transaction and grow our business, and may result in us incurring asset impairment or restructuring charges. These and/or other challenges may arise in connection with our planned acquisition of Otezla® or other acquisition activities, which could have a material adverse effect on our business, results of operations and stock price.

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

During the three months ended September 30, 2019, we had one outstanding stock repurchase program, under which the repurchase activity was as follows:

Period	Total number of shares purchased	Average price paid per share [1]	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program [2]
July 1 - 31	3,084,000	$ 179.11	3,084,000	$ 4,181,496,250
August 1 - 31	1,750,900	$ 194.47	1,750,900	$ 3,840,999,525
September 1 - 30	1,398,500	$ 197.74	1,398,500	$ 3,564,457,656
Total	6,233,400	$ 187.60	6,233,400	

[1] Average price paid per share includes related expenses.

[2] In May 2019, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $5.0 billion.

Item 6. EXHIBITS

Reference is made to the Index to Exhibits included herein.

INDEX TO EXHIBITS

Exhibit No.	Description
2.1	Asset Purchase Agreement, dated August 25, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.2	Amendment No. 1 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on October 17, 2019 and incorporated herein by reference.)
2.3	Irrevocable Guarantee, dated August 25, 2019, by and between Amgen Inc. and Bristol-Myers Squibb Company. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.6	Officer's Certificate of Amgen Inc., dated April 8, 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.)
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	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 1.850% Senior Notes due 2021, 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of May 11, 2017 including forms of the Company's Senior Floating Rate Notes due 2019, Senior Floating Rate Notes due 2020, 1.900% Senior Notes due 2019, 2.200% Senior Notes due 2020 and 2.650% Senior Notes due 2022. (Filed as an exhibit to Form 8-K on May 11, 2017 and incorporated herein by reference.)
4.28	Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated by reference.)
10.1+	Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
10.2+	First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.)
10.3+	Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)

10.4+	Form of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 7, 2018.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2018 on February 13, 2019 and incorporated herein by reference.)
10.5+	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 7, 2018.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2018 on February 13, 2019 and incorporated herein by reference.)
10.6+	Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.7+	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on December 7, 2018.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2018 on February 13, 2019 and incorporated herein by reference.)
10.8+	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on October 24, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
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 October 24, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.11+	Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.12+	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.)
10.13+	First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.14+	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.)
10.15+	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.)
10.16+	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.)
10.17+	Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.18+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.19+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.20+	Agreement between Amgen Inc. and David W. Meline, effective July 21, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2014 on October 29, 2014 and incorporated herein by reference.)
10.21+	Agreement between Amgen Inc. and Jonathan Graham, dated May 11, 2015. (Filed as an exhibit to Form 10-Q/A for the quarter ended June 30, 2015 on August 6, 2015 and incorporated herein by reference.)
10.22+	Agreement between Amgen Inc. and Lori Johnston, dated October 25, 2016. (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.23+	Agreement between Amgen Inc. and Murdo Gordon, dated July 25, 2018. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2018 on October 31, 2018 and incorporated herein by reference.)

10.24	Amended and Restated Credit Agreement, dated July 30, 2014, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent (the "Credit Agreement"). (Filed as an exhibit to Form 8-K on July 30, 2014 and incorporated herein by reference.)
10.25	Amendment No. 1 to the Credit Agreement, dated March 9, 2018, among Amgen Inc., the Banks therein named, and Citibank, N.A., as administrative agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.)
10.26	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.)
10.27	Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.28	Letter Agreement, dated June 25, 2019, by and between Amgen Inc. and UCB Celltech (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2019 on July 31, 2019 and incorporated herein by reference.)
10.29	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.)
10.30	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.)
10.31	Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.32	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.)
10.33	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.)
10.34	Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
10.35	Sourcing and Supply Agreement, dated January 6, 2017, 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-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.36	Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.37	Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.38	Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)

10.39	Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.40	Amendment No. 1 to the Collaboration Agreement, dated March 20, 2018, by and between Novartis Pharma AG and Amgen Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.)
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

(* = filed herewith)

(** = furnished herewith and not “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended)

(+ = management contract or compensatory plan or arrangement)

SIGNATURES

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

Amgen Inc.
(Registrant)

Date: October 29, 2019

By: /S/ DAVID W. MELINE

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

Exhibit 31

CERTIFICATIONS

I, Robert A. Bradway, Chairman of the Board, Chief Executive Officer and President of Amgen Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Amgen Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and

   (d) Disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2019

/s/ ROBERT A. BRADWAY

Robert A. Bradway
Chairman of the Board,
Chief Executive Officer and President

CERTIFICATIONS

I, David W. Meline, Executive Vice President and Chief Financial Officer of Amgen Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Amgen Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and

   (d) Disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2019

/s/ DAVID W. MELINE

David W. Meline

Executive Vice President and Chief Financial Officer

Exhibit 32

Certification of Chief Executive Officer

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Amgen Inc. (the "Company") hereby certifies that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the period endedSeptember 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 29, 2019

/s/ ROBERT A. BRADWAY

Robert A. Bradway

Chairman of the Board,

Chief Executive Officer and President

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Amgen Inc. and will be retained by Amgen Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Certification of Chief Financial Officer

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Amgen Inc. (the "Company") hereby certifies that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the period endedSeptember 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 29, 2019

/s/ DAVID W. MELINE

David W. Meline

Executive Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Amgen Inc. and will be retained by Amgen Inc. and furnished to the Securities and Exchange Commission or its staff upon request.