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 June 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 July 24, 2019, the registrant had 599,701,222 shares of common stock, $0.0001 par value, outstanding.

AMGEN INC.

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Item 1. FINANCIAL STATEMENTS

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

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Revenues:				
Product sales	$ 5,574	$ 5,679	$ 10,860	$ 11,022
Other revenues	297	380	568	591
Total revenues	5,871	6,059	11,428	11,613
Operating expenses:				
Cost of sales	1,012	1,024	2,067	1,968
Research and development	924	869	1,803	1,629
Selling, general and administrative	1,260	1,353	2,414	2,480
Other	(3)	(19)	(6)	(22)
Total operating expenses	3,193	3,227	6,278	6,055
Operating income	2,678	2,832	5,150	5,558
Interest expense, net	332	347	675	685
Interest and other income, net	218	162	403	393
Income before income taxes	2,564	2,647	4,878	5,266
Provision for income taxes	385	351	707	659
Net income	$ 2,179	$ 2,296	$ 4,171	$ 4,607
Earnings per share:				
Basic	$ 3.59	$ 3.50	$ 6.78	$ 6.76
Diluted	$ 3.57	$ 3.48	$ 6.75	$ 6.73
Shares used in calculation of earnings per share:				
Basic	607	656	615	682
Diluted	610	660	618	685

See accompanying notes.

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

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Net income	$ 2,179	$ 2,296	$ 4,171	$ 4,607
Other comprehensive income (loss), net of reclassification adjustments and taxes:				
Losses on foreign currency translation	(4)	(111)	(17)	(82)
(Losses) gains on cash flow hedges	(104)	223	(59)	229
Gains (losses) on available-for-sale securities	153	9	374	(334)
Other	6	—	6	2
Other comprehensive income (loss), net of taxes	51	121	304	(185)
Comprehensive income	$ 2,230	$ 2,417	$ 4,475	$ 4,422

See accompanying notes.

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

	June 30, 2019	December 31, 2018
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,525	$ 6,945
Marketable securities	16,233	22,359
Trade receivables, net	3,801	3,580
Inventories	3,176	2,940
Other current assets	2,011	1,794
Total current assets	30,746	37,618
Property, plant and equipment, net	4,882	4,958
Intangible assets, net	6,813	7,443
Goodwill	14,689	14,699
Other assets	2,243	1,698
Total assets	$ 59,373	$ 66,416
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,001	$ 1,207
Accrued liabilities	6,805	7,862
Current portion of long-term debt	2,816	4,419
Total current liabilities	10,622	13,488
Long-term debt	27,798	29,510
Long-term deferred tax liabilities	763	864
Long-term tax liabilities	7,861	8,770
Other noncurrent liabilities	1,535	1,284
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding — 602.1 shares in 2019 and 629.6 shares in 2018	31,313	31,246
Accumulated deficit	(20,054)	(17,977)
Accumulated other comprehensive loss	(465)	(769)
Total stockholders' equity	10,794	12,500
Total liabilities and stockholders' equity	$ 59,373	$ 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

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

See accompanying notes.

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

	Six months ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net income	$ 4,171	$ 4,607
Depreciation, amortization and other	996	955
Deferred income taxes	(70)	(114)
Other items, net	32	181
Changes in operating assets and liabilities, net of acquisition:		
Trade receivables, net	(228)	(348)
Inventories	(118)	(135)
Other assets	(158)	(232)
Accounts payable	(205)	(329)
Accrued income taxes, net	(257)	(314)
Long-term tax liabilities	(322)	134
Other liabilities	(582)	424
Net cash provided by operating activities	3,259	4,829
Cash flows from investing activities:		
Purchases of marketable securities	(7,250)	(6,733)
Proceeds from sales of marketable securities	217	23,723
Proceeds from maturities of marketable securities	13,617	993
Cash acquired in acquisition, net of cash paid	—	197
Purchases of property, plant and equipment	(260)	(342)
Other	(24)	6
Net cash provided by investing activities	6,300	17,844
Cash flows from financing activities:		
Repayment of debt	(3,650)	(500)
Repurchases of common stock	(5,447)	(13,941)
Dividends paid	(1,781)	(1,816)
Other	(101)	(85)
Net cash used in financing activities	(10,979)	(16,342)
(Decrease) increase in cash and cash equivalents	(1,420)	6,331
Cash and cash equivalents at beginning of period	6,945	3,800
Cash and cash equivalents at end of period	$ 5,525	$ 10,131

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 six months ended June 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 Report on Form 10-Q for the period ended March 31, 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 $8.1 billion and $7.8 billion as of June 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 8, 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, but may be adopted earlier. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. We are currently evaluating the impact that this new standard will have on our condensed consolidated financial statements.

2. 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 June 30,					
	2019			2018		
	US	ROW	Total	US	ROW	Total
Enbrel® (etanercept)	$ 1,315	$ 48	$ 1,363	$ 1,252	$ 50	$ 1,302
Neulasta® (pegfilgrastim)	719	105	824	948	152	1,100
Prolia® (denosumab)	458	240	698	396	214	610
XGEVA® (denosumab)	379	120	499	339	113	452
Aranesp® (darbepoetin alfa)	192	244	436	241	231	472
KYPROLIS® (carfilzomib)	166	101	267	151	112	263
EPOGEN® (epoetin alfa)	223	—	223	250	—	250
Sensipar®/Mimpara® (cinacalcet)	43	79	122	330	90	420
Other products	647	495	1,142	460	350	810
Total product sales[1]	$ 4,142	$ 1,432	5,574	$ 4,367	$ 1,312	5,679
Other revenues			297			380
Total revenues			$ 5,871			$ 6,059

	Six months ended June 30,					
	2019			2018		
	US	ROW	Total	US	ROW	Total
ENBREL	$ 2,421	$ 93	$ 2,514	$ 2,302	$ 105	$ 2,407
Neulasta®	1,612	233	1,845	1,957	298	2,255
Prolia®	848	442	1,290	716	388	1,104
XGEVA®	735	235	970	671	226	897
Aranesp®	374	476	850	466	460	926
KYPROLIS®	320	192	512	288	197	485
EPOGEN®	442	—	442	494	—	494
Sensipar®/Mimpara®	178	157	335	739	178	917
Other products	1,203	899	2,102	881	656	1,537
Total product sales[1]	$ 8,133	$ 2,727	10,860	$ 8,514	$ 2,508	11,022
Other revenues			568			591
Total revenues			$ 11,428			$ 11,613

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

3. Income taxes

The effective tax rates for the three and six months ended June 30, 2019, were 15.0% and 14.5%, respectively, compared with 13.3% and 12.5%, respectively, for the corresponding periods of the prior year.

The increase in our effective tax rates for the three and six months ended June 30, 2019, was 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 10.5% rate.

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 and regulations and the interpretations of the relevant facts. As previously disclosed, we received a Revenue Agent Report (RAR) from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. 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 six months ended June 30, 2019, the gross amounts of our unrecognized tax benefits (UTBs) increased $60 million and $110 million, respectively, as a result of tax positions taken during the current year. Substantially all of the UTBs as of June 30, 2019, if recognized, would affect our effective tax rate.

4. Earnings per share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which include primarily shares that may be issued under our stock option, restricted stock and performance unit award programs (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 June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Income (Numerator):				
Net income for basic and diluted EPS	$ 2,179	$ 2,296	$ 4,171	$ 4,607
Shares (Denominator):				
Weighted-average shares for basic EPS	607	656	615	682
Effect of dilutive securities	3	4	3	3
Weighted-average shares for diluted EPS	610	660	618	685
Basic EPS	$ 3.59	$ 3.50	$ 6.78	$ 6.76
Diluted EPS	$ 3.57	$ 3.48	$ 6.75	$ 6.73

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

5. 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 June 30, 2019	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 2,709	$ 10	$ (2)	$ 2,717
U.S. Treasury bills	3,497	—	—	3,497
Other government-related debt securities:				
U.S.	112	—	—	112
Foreign and other	962	18	(3)	977
Corporate debt securities:				
Financial	2,755	19	(1)	2,773
Industrial	2,400	14	(6)	2,408
Other	558	4	—	562
Residential-mortgage-backed securities	1,335	2	(4)	1,333
Other mortgage- and asset-backed securities	469	—	(6)	463
Money market mutual funds	3,886	—	—	3,886
Other short-term interest-bearing securities	2,389	—	—	2,389
Total interest-bearing securities	$ 21,072	$ 67	$ (22)	$ 21,117

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	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 4,884	$ 6,365
Marketable securities	16,233	22,359
Total interest-bearing securities	$ 21,117	$ 28,724

Cash and cash equivalents in the above table excludes bank account cash of $641 million and $580 million as of June 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	June 30, 2019	December 31, 2018
Maturing in one year or less	$ 9,872	$ 17,424
Maturing after one year through three years	5,730	3,356
Maturing after three years through five years	2,961	5,168
Maturing after five years through ten years	758	885
Mortgage- and asset-backed securities	1,796	1,891
Total interest-bearing securities	$ 21,117	$ 28,724

For the three months ended June 30, 2019 and 2018, realized gains on interest-bearing securities were $1 million and $5 million, respectively, and realized losses on interest-bearing securities were $3 million and $120 million, respectively. For the six months ended June 30, 2019 and 2018, realized gains on interest-bearing securities were $2 million and $22 million, respectively, and realized losses on interest-bearing securities were $8 million and $271 million, respectively. Realized gains and losses on interest-bearing securities are recorded in Interest and other income, net, in the Condensed Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

The fair values and gross unrealized losses of 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 June 30, 2019	Fair values	Unrealized losses	Fair values	Unrealized losses
U.S. Treasury notes	$ 105	$ —	$ 724	$ (2)
Other government-related debt securities:				
U.S.	—	—	48	—
Foreign and other	6	—	115	(3)
Corporate debt securities:				
Financial	121	—	320	(1)
Industrial	191	(3)	500	(3)
Other	30	—	40	—
Residential-mortgage-backed securities	93	—	685	(4)
Other mortgage- and asset-backed securities	—	—	401	(6)
Total	$ 546	$ (3)	$ 2,833	$ (19)

Types of securities as of December 31, 2018	Less than 12 months		12 months or more	
	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 June 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 $287 million and $176 million as of June 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 six months ended June 30, 2019 and 2018.

As of June 30, 2019 and December 31, 2018, respectively, we held investments of $169 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 six months ended June 30, 2019 and 2018.

Limited partnership investments

We held limited partnership investments of $312 million and $285 million as of June 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 June 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 six months ended June 30, 2019 and 2018.

6. Inventories

Inventories consisted of the following (in millions):

	June 30, 2019	December 31, 2018
Raw materials	$ 294	$ 257
Work in process	1,788	1,660
Finished goods	1,094	1,023
Total inventories	$ 3,176	$ 2,940

7. Goodwill and other intangible assets

Goodwill

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

	Six months ended June 30, 2019
Beginning balance	$ 14,699
Currency translation adjustment	(10)
Ending balance	$ 14,689

Other intangible assets

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

	June 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	$ 12,563	$ (7,812)	$ 4,751	$ 12,573	$ (7,479)	$ 5,094
Licensing rights	3,693	(2,174)	1,519	3,772	(2,032)	1,740
Marketing-related rights	1,209	(959)	250	1,297	(1,019)	278
Research and development technology rights	1,148	(910)	238	1,148	(872)	276
Total finite-lived intangible assets	18,613	(11,855)	6,758	18,790	(11,402)	7,388
Indefinite-lived intangible assets:						
In-process research and development	55	—	55	55	—	55
Total other intangible assets	$ 18,668	$ (11,855)	$ 6,813	$ 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.

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 June 30, 2019 and 2018, we recognized amortization associated with our finite-lived intangible assets of $315 million and $332 million, respectively. During the six months ended June 30, 2019 and 2018, we recognized amortization associated with our finite-lived intangible assets of $630 million and $652 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 six months ending December 31, 2019, and the years ending December 31, 2020, 2021, 2022, 2023 and 2024, are $0.6 billion, $1.2 billion, $1.0 billion, $0.9 billion, $0.9 billion and $0.8 billion, respectively.

8. 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 lease terms of 12 months or less are expensed on a straight-line basis over the lease 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 any residual value guarantees nor impose any 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	June 30, 2019
Assets:	
Other assets	$ 430
Liabilities:	
Accrued liabilities	$ 134
Other noncurrent liabilities	363
Total lease liabilities	$ 497

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

Lease costs	Three months ended June 30, 2019	Six months ended June 30, 2019
Operating[1]	$ 51	$ 99
Sublease income	(9)	(17)
Total net lease costs	$ 42	$ 82

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

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

Maturity dates	Operating leases
Remaining six months ending December 31, 2019	$ 69
2020	152
2021	132
2022	73
2023	62
Thereafter	48
Total lease payments[1]	536
Less imputed interest	(39)
Present value of lease liabilities	$ 497

[1] Includes future rental commitments for abandoned leases of $200 million. We expect to receive total future rental income of $158 million related to noncancelable subleases for abandoned facilities.

The weighted-average remaining lease term and weighted-average discount rate of our leases were 4.2 years and 3.32%, respectively, as of June 30, 2019.

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

	Three months ended June 30, 2019	Six months ended June 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 39	$ 73
ROU assets obtained in exchange for lease obligations:		
Operating leases	$ 46	$ 54

9. Financing arrangements

Our borrowings consisted of the following (in millions):

	June 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)	768	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)	1,422	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)	717	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)	853	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)	603	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)	889	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	(882)	(896)
Fair value adjustments	295	(53)
Total carrying value of debt	30,614	33,929
Less current portion	(2,816)	(4,419)
Total long-term debt	$ 27,798	$ 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.

10. 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
Total stock repurchases	28.9	$ 5,380	74.6	$ 13,977

* 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 June 30, 2019, $4.7 billion of authorization remained available under our stock repurchase program.

Dividends

In March 2019 and December 2018, the Board of Directors declared quarterly cash dividends of $1.45 per share, which were paid in June 2019 and March 2019, respectively.

Accumulated other comprehensive income (loss)

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

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 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)

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

Components of AOCI	Three months ended June 30, 2019	2018	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract gains (losses)	$ 22	$ (20)	Product sales
Cross-currency swap contract gains (losses)	14	(298)	Interest and other income, net
	36	(318)	Income before income taxes
	(8)	68	Provision for income taxes
	$ 28	$ (250)	Net income
Available-for-sale securities:			
Net realized losses	$ (2)	$ (115)	Interest and other income, net
	—	1	Provision for income taxes
	$ (2)	$ (114)	Net income

Components of AOCI	Six months ended June 30, 2019	2018	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract gains (losses)	$ 36	$ (54)	Product sales
Cross-currency swap contract losses	(28)	(134)	Interest and other income, net
	8	(188)	Income before income taxes
	(2)	40	Provision for income taxes
	$ 6	$ (148)	Net income
Available-for-sale securities:			
Net realized losses	$ (6)	$ (249)	Interest and other income, net
	—	2	Provision for income taxes
	$ (6)	$ (247)	Net income

11. Fair value measurement

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

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

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

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

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

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 June 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	$ 2,717	$ —	$ —	$ 2,717
U.S. Treasury bills	3,497	—	—	3,497
Other government-related debt securities:				
U.S.	—	112	—	112
Foreign and other	—	977	—	977
Corporate debt securities:				
Financial	—	2,773	—	2,773
Industrial	—	2,408	—	2,408
Other	—	562	—	562
Residential-mortgage-backed securities	—	1,333	—	1,333
Other mortgage- and asset-backed securities	—	463	—	463
Money market mutual funds	3,886	—	—	3,886
Other short-term interest-bearing securities	—	2,389	—	2,389
Equity securities	287	—	—	287
Derivatives:				
Foreign currency contracts	—	205	—	205
Cross-currency swap contracts	—	150	—	150
Interest rate swap contracts	—	258	—	258
Total assets	$ 10,387	$ 11,630	$ —	$ 22,017
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 15	$ —	$ 15
Cross-currency swap contracts	—	515	—	515
Contingent consideration obligations	—	—	63	63
Total liabilities	$ —	$ 530	$ 63	$ 593

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

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

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

Derivatives

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

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, 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 12, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We 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 12, Derivative instruments.

Contingent consideration obligations

As a result of our business acquisitions, 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 six months ended June 30, 2019 and 2018, were not material.

During the three and six months ended June 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.

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 June 30, 2019 and December 31, 2018, the aggregate fair values of our borrowings were $33.4 billion and $35.0 billion, respectively, and the carrying values were $30.6 billion and $33.9 billion, respectively.

12. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we 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 both June 30, 2019 and December 31, 2018, we had outstanding foreign currency forward contracts with aggregate notional amounts of $4.5 billion and outstanding foreign currency option contracts with aggregate notional amounts of $21 million. 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 June 30, 2019, were as follows (notional amounts in millions):

	Foreign currency			U.S. dollars		
Hedged notes	**Notional amounts**		**Interest rates**	**Notional amounts**		**Interest rates**
2.125% 2019 euro Notes	€	675	2.1%	$	864	2.6%
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%

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 six months ended June 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 June 30,		Six months ended June 30,	
Derivatives in cash flow hedging relationships	**2019**	**2018**	**2019**	**2018**
Foreign currency contracts	$ (16)	$ 281	$ 69	$ 192
Cross-currency swap contracts	(80)	(315)	(135)	(77)
Total unrealized (losses) gains	$ (96)	$ (34)	$ (66)	$ 115

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 June 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	**June 30, 2019**	**December 31, 2018**	**June 30, 2019**	**December 31, 2018**
Current portion of long-term debt	$ —	$ 2,396	$ —	$ (3)
Long-term debt	$ 9,712	$ 9,361	$ 295	$ (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 June 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 June 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 June 30, 2019			Six months ended June 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	$ 5,574	$ 218	$ (332)	$ 10,860	$ 403	$ (675)
The effects of cash flow and fair value hedging:						
Gains (losses) on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency contracts	$ 22	$ —	$ —	$ 36	$ —	$ —
Cross-currency swap contracts	$ —	$ 14	$ —	$ —	$ (28)	$ —
(Losses) gains on fair value hedging relationships—interest rate swap agreements:						
Hedged items[1]	$ —	$ —	$ (218)	$ —	$ —	$ (348)
Derivatives designated as hedging instruments	$ —	$ —	$ 218	$ —	$ —	$ 351

	Three months ended June 30, 2018			Six months ended June 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	$ 5,679	$ 162	$ (347)	$ 11,022	$ 393	$ (685)
The effects of cash flow and fair value hedging:						
Losses on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency contracts	$ (20)	$ —	$ —	$ (54)	$ —	$ —
Cross-currency swap contracts	$ —	$ (298)	$ —	$ —	$ (134)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:						
Hedged items[1]	$ —	$ —	$ 58	$ —	$ —	$ 230
Derivatives designated as hedging instruments	$ —	$ —	$ (51)	$ —	$ —	$ (215)

[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 June 30, 2019, we expected to reclassify $86 million of net losses 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 June 30, 2019 and December 31, 2018, the total notional amounts of these foreign currency forward contracts were $1.2 billion and $0.7 billion, respectively. Gains and losses recognized in earnings for our derivative instruments not designated as hedging instruments were not material for the three and six months ended June 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	
June 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	$ 203	Accrued liabilities/ Other noncurrent liabilities	$ 15
Cross-currency swap contracts	Other current assets/ Other assets	150	Accrued liabilities/ Other noncurrent liabilities	515
Interest rate swap contracts	Other current assets/ Other assets	258	Accrued liabilities/ Other noncurrent liabilities	—
Total derivatives designated as hedging instruments		611		530
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	2	Accrued liabilities	—
Total derivatives not designated as hedging instruments		2		—
Total derivatives		$ 613		$ 530

	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 of June 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 are included in Net cash provided by operating activities in the Condensed Consolidated Statements of Cash Flows.

13. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See our Annual Report on Form 10-K for the year ended December 31, 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; and in 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.

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 Report on Form 10-Q for the period ended March 31, 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 Report on Form 10-Q for the period ended March 31, 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 July 16, 2019, Novartis Pharma AG (Novartis) filed an amended complaint in the U.S. District Court for the Southern District of New York adding a claim for breach of contract alleging Novartis is owed amounts associated with 2018 budget overruns and Amgen responded with a counterclaim alleging additional breaches by Novartis of the collaboration agreements between the parties.

Repatha® (evolocumab) Patent Litigation

On June 6, 13 and 21, 2019, the U.S. District Court for the District of Delaware (the Delaware District Court) held evidentiary hearings on Amgen's motion for a permanent injunction against PRALUENT®. The Delaware District Court has scheduled an August 8, 2019 hearing on the post-trial motion for a judgment notwithstanding the jury verdict filed by Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc., and Regeneron Pharmaceuticals, Inc.

Sensipar® (cinacalcet) Litigation

Cipla Ltd. v. Amgen Inc.

On May 2, 2019, the Delaware District Court denied Amgen's motion for preliminary injunction in the lawsuit by Cipla Limited and Cipla USA, Inc. (collectively, Cipla) seeking a declaration that provisions of its settlement agreement with Amgen have been triggered by the at-risk launch of a generic cinacalcet product by Teva Pharmaceutical Industries Ltd. (Teva). On the same day, Amgen filed its notice of appeal of the Delaware District Court's denial of Amgen's motion for preliminary injunction in the United States Court of Appeals for the Third Circuit (the Third Circuit Court of Appeals). On May 3, 2019, Amgen filed a motion for injunction pending appeal in the Delaware District Court, which was denied on May 9, 2019. On May 13, 2019, Amgen filed a motion for injunction pending appeal and expedited briefing in the Third Circuit Court of Appeals. On May 23, 2019, the Third Circuit Court of Appeals denied the motion for injunction pending appeal and granted the request for expedited briefing. On July 16, 2019, the Third Circuit Court of Appeals affirmed the Delaware District Court's decision denying Amgen's motion for a preliminary injunction. With respect to Cipla's pending claims, the Delaware District Court has given Cipla until July 31, 2019 to amend its complaint.

Amgen Inc. v. Amneal Pharmaceuticals LLC, et al. Abbreviated New Drug Application (ANDA) Patent Litigation

On June 13, 2019, the Delaware District Court held a hearing on the motion filed by Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, Sun) to enforce the settlement agreement entered between Amgen and Sun. By its complaint, Sun is contending that its generic cinacalcet product should not be held off the U.S. market.

On July 17, 2019, Amgen filed a motion requesting the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court) to vacate the Delaware District Court's noninfringement judgment in favor of Watson Laboratories, Inc. and Actavis Pharma, Inc. and direct entry of the parties' proposed consent judgment.

KYPROLIS® (carfilzomib) ANDA Patent Litigation

On May 6, 2019, the Delaware District Court commenced trial in the *Onyx Therapeutics, Inc. v. Cipla Limited., et al*. consolidated case. On May 7, 2019, the Delaware District Court signed consent judgments filed prior to trial by Onyx Therapeutics, Inc. (Onyx Therapeutics) and each of Aurobindo Pharma USA, Inc. (Aurobindo); InnoPharma Inc. (InnoPharma); Sagent Pharmaceuticals, Inc. (Sagent); Apotex Inc. and Apotex Corp. (collectively, Apotex); Fresenius Kabi USA, Inc. and Fresenius Kabi USA, LLC (collectively, Fresenius) and signed a consent judgment filed that same day by Onyx Therapeutics and MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (collectively, MSN). On May 14, 2019, the Delaware District Court signed consent judgments filed during trial by Onyx Therapeutics and each of Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, DRL) and Breckenridge Pharmaceutical, Inc. (Breckenridge). In the consent judgments between Onyx Therapeutics and each of Aurobindo, InnoPharma, Sagent, Apotex, Fresenius, DRL, and Breckenridge, the parties stipulated to entry of: (1) judgment dismissing with prejudice all of the parties' claims, counterclaims, affirmative defenses and demands; and (2) an injunction prohibiting infringement of U.S. Patent Nos. 7,417,042; 7,737,112 (the '112 Patent); and 8,207,125 by the manufacture, use, sale, offer to sell, or importation into the United States of the applicable defendant's carfilzomib product unless specifically authorized pursuant to the applicable confidential settlement agreement. In the consent judgment between Onyx Therapeutics and MSN, the parties stipulated to entry of: (1) judgment dismissing with prejudice all of the parties' claims, counterclaims, affirmative defenses and demands; and (2) an injunction prohibiting infringement of the '112 Patent by the manufacture, use, sale, offer to sell, or importation into the United States of MSN's carfilzomib product unless specifically authorized pursuant to the confidential settlement agreement. On May 16, 2019, trial concluded between Onyx Therapeutics and the lone remaining defendant, Cipla. The parties await the judgment of the Delaware District Court.

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

Coherus Neulasta® Patent Litigation

On July 29, 2019, the Federal Circuit Court affirmed the Delaware District Court's final judgment dismissing Amgen's lawsuit against Coherus BioSciences, Inc. (Coherus) for infringement of U.S. Patent No. 8,273,707.

Sandoz NEUPOGEN® / Neulasta® Patent Litigation

On May 8, 2019, the Federal Circuit Court affirmed the U.S. District Court for the Northern District of California's grant of summary judgment of noninfringement of U.S. Patent Nos. 8,940,878 and 6,162,427 by Sandoz Inc., Sandoz International GmbH and Sandoz GmbH. On June 7, 2019, Amgen and Amgen Manufacturing, Limited (AML) filed a petition for rehearing *en banc* in the Federal Circuit Court.

On May 13, 2019, Sandoz Inc. voluntarily dismissed, without prejudice, the separate lawsuit it had filed in the U.S. District Court for the Northern District of California against Amgen and AML seeking a judgment of noninfringement and invalidity of the U.S. Patent No. 9,643,997 (the '997 Patent).

Mylan Neulasta® Patent Litigation

On June 13, 2019, the District Court for the Western District of Pennsylvania granted the request by Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. (collectively, Mylan) for a temporary stay pending the outcome of Amgen's Federal Circuit Court appeal in the Coherus Neulasta® Patent Litigation, and Amgen's petition for *en banc* review of the Federal Circuit Court's May 8, 2019 decision in the Sandoz NEUPOGEN® / Neulasta® Patent Litigation (each case discussed above).

Tanvex NEUPOGEN® Patent Litigation

On July 23, 2019, Amgen filed a lawsuit in the U.S. District Court for the Southern District of California against Tanvex BioPharma USA, Inc., Tanvex BioPharma, Inc., and Tanvex Biologics Corp. (collectively, Tanvex) for infringement of U.S. Patent No. 9,856,287 (the ’287 Patent) in accordance with the patent provisions of the Biologics Price Competition and Innovation Act (BPCIA). This lawsuit stems from Tanvex’s submissions of an application for U.S. Food and Drug Administration (FDA) licensure of a filgrastim product as biosimilar to Amgen’s NEUPOGEN®. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Tanvex from infringing the ’287 Patent.

Coherus Neulasta® Trade Secret Litigation

Following a May 1, 2019 settlement between Amgen and Coherus, on May 2, 2019, pursuant to a joint request regarding settlement, the Ventura County Superior Court dismissed Amgen’s claims against Coherus with prejudice.

Patent Trial and Appeal Board Patent Challenges

On May 20, 2019, the U.S. Patent and Trademark Office’s Patent Trial and Appeal Board (PTAB) issued a decision denying Apotex’s request for rehearing on the PTAB’s finding and *sua sponte* amending the final decision with a finding the one remaining claim in Amgen’s U.S. Patent No. 8,952,138 is unpatentable. On July 22, 2019, Amgen filed a notice of appeal to the Federal Circuit Court with respect to all claims held to be unpatentable.

On June 8, 2019, Fresenius Kabi USA, LLC and Fresenius Kabi SwissBioSim GmbH filed a petition seeking to institute inter partes review (IPR) proceedings before the PTAB to challenge the patentability of the ’997 Patent. The ’997 Patent is also among the patents at issue in the Mylan Neulasta® Patent Litigation, the previously-disclosed litigation between Amgen and Kashiv Biosciences, LLC (formerly known as Adello Biologics, LLC), Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals, Inc., and the previously-disclosed litigation between Amgen and Pfizer Inc. and Hospira Inc. Amgen’s patent owner preliminary response to this IPR petition is due September 11, 2019, after which the PTAB will have three months to render a decision regarding whether to institute PTAB trial proceedings on the ’997 Patent.

Patent Litigation Relating to our Biosimilar Products

AMJEVITA™ (adalimumab-atto) / AMGEVITA™ Patent Litigation

As previously disclosed, Amgen has been sued in a number of European countries by Fresenius Kabi Deutschland GmbH (Fresenius), alleging that AMGEVITA™ infringes various patents of Fresenius and seeking, among other remedies, injunctive relief prohibiting patent infringement. In May 2019, the parties acted jointly, to the extent necessary, to withdraw from and/or seek dismissal of the lawsuits.

KANJINTI™ (trastuzumab) Patent Litigation

On July 10, 2019, Genentech, Inc. (Genentech) filed a motion asking the Delaware District Court for a temporary restraining order and preliminarily injunction prohibiting Amgen from commercially launching, marketing or selling KANJINTI™ until the Delaware District Court renders a decision on the merits of Genentech’s asserted U.S. Patent Nos. 6,627,196; 7,371,379; and 10,160,811. Following Amgen’s opposition, on July 18, 2019, the Delaware District Court denied Genentech’s motion. On July 19, 2019, Genentech filed a notice of appeal and a motion requesting the Federal Circuit Court to enter an injunction prohibiting Amgen from continuing with its launch of KANJINTI™ until final resolution of Genentech’s appeal. On July 24, 2019, the Delaware District Court entered an order dismissing City of Hope as a party to the lawsuit and dismissing with prejudice Genentech’s claims for infringement of a number of expired patents, leaving eight patents asserted by Genentech in the litigation.

MVASI™ (bevacizumab-awwb) Patent Litigation

On July 10, 2019, Genentech, alleging that Amgen’s notice of commercial marketing pursuant to the BPCIA is insufficient, filed motions asking the Delaware District Court for a temporary restraining order and enforcement of the BPCIA to prohibit Amgen from commercially marketing MVASI™ until Amgen has provided new notice and waited until the expiry of the notice period. Following Amgen’s opposition, on July 18, 2019, the Delaware District Court denied Genentech’s motions. On July 19, 2019, Genentech filed a notice of appeal and a motion requesting the Federal Circuit Court to enter an injunction prohibiting Amgen from marketing MVASI™ until final resolution of Genentech’s appeal.

Antitrust Class Actions

Humira® Biosimilar Antitrust Class Actions

As previously disclosed, in March and April 2019, ten purported class actions against Amgen, along with AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively, AbbVie), were filed in U.S. District Court for the Northern District of Illinois (the Illinois Northern District Court). In April and May 2019, two additional purported class actions against Amgen and AbbVie were filed in the Illinois Northern District Court. The additional cases are captioned: *Louisiana Health Service & Indemnity Co., d/b/a Blue Cross and Blue Shield of Louisiana, and HMO Louisiana, Inc. v. AbbVie Inc., et al.* (April 30, 2019) (Louisiana Health); and *Cleveland Bakers and Teamsters Health and Welfare Fund v. AbbVie Inc., et al.* (May 10, 2019) (Cleveland Bakers, and together with Louisiana Health, the New Humira® Antitrust Class Actions). In each of the New Humira® Antitrust Class Actions, the plaintiffs bring federal antitrust claims along with various state law claims under common law and antitrust, consumer protection, and unfair competition statutes. The plaintiffs in the New Humira® Antitrust Class Actions specifically allege that AbbVie has unlawfully monopolized the alleged market for Humira® and biosimilars of Humira®, including by creating an allegedly unlawful so-called patent thicket around Humira®. The plaintiffs in the New Humira® Antitrust Class Actions allege that AbbVie and Amgen entered into an allegedly unlawful settlement agreement under which Amgen allegedly agreed to delay its entry into the U.S. market with AMGEVITA™, its Humira® biosimilar, in exchange for an alleged promise of exclusivity as the sole Humira® biosimilar in that market for five months, beginning in January 2023. In each of the New Humira® Antitrust Class Actions, plaintiffs seek injunctive relief, treble damages and attorney's fees on behalf of a putative class of third-party payers and/or consumers that have indirectly purchased, paid for or provided reimbursement for Humira® in the United States. On June 4, 2019, the Illinois Northern District Court entered an order consolidating the twelve purported class action cases for pre-trial purposes. On June 13, 2019, the Illinois Northern District Court entered an order requiring the plaintiffs to file a consolidated complaint by August 12, 2019.

Sensipar® Antitrust Class Actions

As previously disclosed, a plaintiff in one of the class action lawsuits against Amgen and various entities affiliated with Teva filed a motion seeking to have the four class action lawsuits consolidated and designated as a multidistrict litigation (MDL) in the U.S. District Court for the Eastern District of Pennsylvania, and a different plaintiff in another of the class action lawsuits filed a motion seeking to have the four class action lawsuits, along with *Cipla Ltd. v. Amgen Inc.*, consolidated and designated as a MDL in the Delaware District Court. On July 25, 2019, the MDL panel held a hearing on the motions to consolidate.

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 Report on Form 10-Q for the period ended March 31, 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), Parsabiv® (etelcalcetide), Repatha®, NEUPOGEN®, BLINCYTO® (blinatumomab), Aimovig® (erenumab-aooe), AMGEVITA™, KANJINTI™, EVENITY™ (romosozumab-aqqg), IMLYGIC® (talimogene laherparepvec) 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 March 31, 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 Report on Form 10-Q for the period ended March 31, 2019.

Products/Pipeline

Bone health

EVENITY™

- In June 2019, we and UCB, our global collaboration partner in the development of EVENITY™, announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a negative opinion on the Marketing Authorization Application for EVENITY™ for the treatment of severe osteoporosis. In July 2019, UCB submitted a written notice to the EMA requesting a reexamination of the CHMP opinion.

Neuroscience

AMG 520 / CNP520

- In July 2019, we and Novartis discontinued investigating AMG 520 / CNP520, a small-molecule inhibitor of beta-site amyloid precursor protein-cleaving enzyme-1 (BACE), for the prevention of Alzheimer's disease.

Biosimilars

ABP 710 (biosimilar infliximab)

- In July 2019, we announced that the FDA has set a December 14, 2019 Biosimilar User Fee Act target action date for the Biologics License Application of ABP 710, a biosimilar candidate to REMICADE®.

KANJINTI™

- In June 2019, we and Allergan plc (Allergan) announced that the FDA approved KANJINTI™ for all approved indications of the reference product Herceptin® (trastuzumab) for the treatment of HER2-overexpressing adjuvant and metastatic breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. In July 2019, we and Allergan announced the launch of KANJINTI™ in the United States.

MVASI™

- In July 2019, we and Allergan announced the launch of MVASI™ in the United States.

For a discussion of litigations relating to KANJINTI™ and MVASI™, 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.

Selected financial information

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

	Three months ended June 30,			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
Product sales						
U.S.	$ 4,142	$ 4,367	(5)%	$ 8,133	$ 8,514	(4)%
ROW	1,432	1,312	9 %	2,727	2,508	9 %
Total product sales	5,574	5,679	(2)%	10,860	11,022	(1)%
Other revenues	297	380	(22)%	568	591	(4)%
Total revenues	$ 5,871	$ 6,059	(3)%	$ 11,428	$ 11,613	(2)%
Operating expenses	$ 3,193	$ 3,227	(1)%	$ 6,278	$ 6,055	4 %
Operating income	$ 2,678	$ 2,832	(5)%	$ 5,150	$ 5,558	(7)%
Net income	$ 2,179	$ 2,296	(5)%	$ 4,171	$ 4,607	(9)%
Diluted EPS	$ 3.57	$ 3.48	3 %	$ 6.75	$ 6.73	— %
Diluted shares	610	660	(8)%	618	685	(10)%

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 months ended June 30, 2019, driven primarily by a decline in net selling price, offset partially by higher unit demand. Total product sales decreased for the six months ended June 30, 2019, driven primarily by a decline in net selling price and unfavorable changes in inventory, 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 six months ended June 30, 2019, driven primarily by lower milestone payments, offset partially by higher royalties.

Operating expenses for the three months ended June 30, 2019, were relatively flat. Operating expenses increased for the six months ended June 30, 2019, driven primarily by increased spending in research and early pipeline in support of our oncology programs and higher cost of sales.

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 six months ended June 30, 2019 and 2018.

Results of operations

Product sales

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

	Three months ended June 30,			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
ENBREL	$ 1,363	$ 1,302	5 %	$ 2,514	$ 2,407	4 %
Neulasta®	824	1,100	(25)%	1,845	2,255	(18)%
Prolia®	698	610	14 %	1,290	1,104	17 %
XGEVA®	499	452	10 %	970	897	8 %
Aranesp®	436	472	(8)%	850	926	(8)%
KYPROLIS®	267	263	2 %	512	485	6 %
EPOGEN®	223	250	(11)%	442	494	(11)%
Sensipar®/Mimpara®	122	420	(71)%	335	917	(63)%
Other products	1,142	810	41 %	2,102	1,537	37 %
Total product sales	$ 5,574	$ 5,679	(2)%	$ 10,860	$ 11,022	(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 Report on Form 10-Q for the period ended March 31, 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 June 30,			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
ENBREL — U.S.	$ 1,315	$ 1,252	5 %	$ 2,421	$ 2,302	5 %
ENBREL — Canada	48	50	(4)%	93	105	(11)%
Total ENBREL	$ 1,363	$ 1,302	5 %	$ 2,514	$ 2,407	4 %

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

In April 2019, the 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 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 June 30,			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
Neulasta®— U.S.	$ 719	$ 948	(24)%	$ 1,612	$ 1,957	(18)%
Neulasta®— ROW	105	152	(31)%	233	298	(22)%
Total Neulasta®	$ 824	$ 1,100	(25)%	$ 1,845	$ 2,255	(18)%

The decreases in global Neulasta® sales for the three and six months ended June 30, 2019, were driven by lower net selling price and the impact of biosimilar competition on 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 relating to these and other biosimilars, 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.

Prolia®

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

	Three months ended June 30,			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
Prolia® — U.S.	$ 458	$ 396	16%	$ 848	$ 716	18%
Prolia® — ROW	240	214	12%	442	388	14%
Total Prolia®	$ 698	$ 610	14%	$ 1,290	$ 1,104	17%

The increases in global Prolia® sales for the three and six months ended June 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 June 30,			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
XGEVA® — U.S.	$ 379	$ 339	12%	$ 735	$ 671	10%
XGEVA® — ROW	120	113	6%	235	226	4%
Total XGEVA®	$ 499	$ 452	10%	$ 970	$ 897	8%

The increases in global XGEVA® sales for the three and six months ended June 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 June 30,			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
Aranesp® — U.S.	$ 192	$ 241	(20)%	$ 374	$ 466	(20)%
Aranesp® — ROW	244	231	6 %	476	460	3 %
Total Aranesp®	$ 436	$ 472	(8)%	$ 850	$ 926	(8)%

The decreases in global Aranesp® sales for the three and six months ended June 30, 2019, were driven 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 June 30, 2019			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
KYPROLIS® — U.S.	$ 166	$ 151	10 %	$ 320	$ 288	11 %
KYPROLIS® — ROW	101	112	(10)%	192	197	(3)%
Total KYPROLIS®	$ 267	$ 263	2 %	$ 512	$ 485	6 %

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

We are engaged in litigation with two related companies that are challenging our material patents related to KYPROLIS® and 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 June 30,			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
EPOGEN® — U.S.	$ 223	$ 250	(11)%	$ 442	$ 494	(11)%

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

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 relating to one of these biosimilars, 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.

Sensipar®/Mimpara®

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

	Three months ended June 30,			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
Sensipar® — U.S.	$ 43	$ 330	(87)%	$ 178	$ 739	(76)%
Sensipar®/Mimpara® — ROW	79	90	(12)%	157	178	(12)%
Total Sensipar®/Mimpara®	$ 122	$ 420	(71)%	$ 335	$ 917	(63)%

The decreases in global Sensipar®/Mimpara® sales for the three and six months ended June 30, 2019, were driven primarily by the impact of at-risk launches by generic competitors.

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 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 will 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 June 30,			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
Nplate®— U.S.	$ 122	$ 107	14 %	236	219	8 %
Nplate®— ROW	79	72	10 %	154	139	11 %
Vectibix®— U.S.	79	68	16 %	157	143	10 %
Vectibix®— ROW	117	105	11 %	209	199	5 %
Parsabiv® — U.S.	148	66	*	257	102	*
Parsabiv® — ROW	20	7	*	37	12	*
Repatha®— U.S.	91	98	(7)%	174	182	(4)%
Repatha®— ROW	61	50	22 %	119	89	34 %
NEUPOGEN®— U.S.	55	63	(13)%	105	128	(18)%
NEUPOGEN®— ROW	20	39	(49)%	43	77	(44)%
BLINCYTO® — U.S.	39	34	15 %	79	64	23 %
BLINCYTO® — ROW	39	26	50 %	68	45	51 %
Aimovig® — U.S.	83	2	*	142	2	*
Biosimilars — ROW	82	2	*	137	2	*
EVENITY™ — U.S.	3	—	*	3	—	*
EVENITY™— ROW	25	—	*	42	—	*
Other — U.S.	27	22	23 %	50	41	22 %
Other — ROW	52	49	6 %	90	93	(3)%
Total other products	$ 1,142	$ 810	41 %	$ 2,102	$ 1,537	37 %
Total U.S. — other products	$ 647	$ 460	41 %	$ 1,203	$ 881	37 %
Total ROW — other products	495	350	41 %	899	656	37 %
Total other products	$ 1,142	$ 810	41 %	$ 2,102	$ 1,537	37 %

* Change in excess of 100%.

Operating expenses

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

	Three months ended June 30,			Six months ended June 30,		
	2019	2018	Change	2019	2018	Change
Operating expenses:						
Cost of sales	$ 1,012	$ 1,024	(1)%	$ 2,067	$ 1,968	5 %
% of product sales	18.2%	18.0%		19.0%	17.9%	
% of total revenues	17.2%	16.9%		18.1%	16.9%	
Research and development	$ 924	$ 869	6 %	$ 1,803	$ 1,629	11 %
% of product sales	16.6%	15.3%		16.6%	14.8%	
% of total revenues	15.7%	14.3%		15.8%	14.0%	
Selling, general and administrative	$ 1,260	$ 1,353	(7)%	$ 2,414	$ 2,480	(3)%
% of product sales	22.6%	23.8%		22.2%	22.5%	
% of total revenues	21.5%	22.3%		21.1%	21.4%	
Other	$ (3)	$ (19)	(84)%	$ (6)	$ (22)	(73)%

Cost of sales

Cost of sales increased to 17.2% of total revenues for the three months ended June 30, 2019, driven primarily by unfavorable product mix, offset partially by the benefit of Hurricane Maria insurance proceeds and lower manufacturing costs.

Cost of sales increased to 18.1% of total revenues for the six months ended June 30, 2019, driven primarily by unfavorable product mix and higher manufacturing costs, offset partially by lower royalty costs 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 six months ended June 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 June 30, 2019, was driven primarily by lower discretionary general and administrative expenses and the end of certain amortization of intangible assets in 2018.

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

Other

Other operating expenses for the three and six months ended June 30, 2019 and 2018, include changes in the fair values of contingent consideration liabilities related to business combinations. Other operating expenses included expenses related to legal proceedings in the second 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 June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Interest expense, net	$ 332	$ 347	$ 675	$ 685
Interest and other income, net	$ 218	$ 162	$ 403	$ 393
Provision for income taxes	$ 385	$ 351	$ 707	$ 659
Effective tax rate	15.0%	13.3%	14.5%	12.5%

Interest expense, net

The decreases in Interest expense, net, for the three and six months ended June 30, 2019, was due primarily to a reduction in outstanding long-term debt as a result of maturities in the current year, offset partially by rising interest rates on variable-rate debt.

Interest and other income, net

The increases in Interest and other income, net, for the three and six months ended June 30, 2019 was due primarily to lower losses on sales of investments in interest-bearing securities, offset partially by reduced interest income as a result of lower average cash balances and lower gains on our strategic equity investments. In addition, the increase for the six-month period was 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 and six months ended June 30, 2019, was due primarily to a prior-year tax benefit associated with intercompany sales under U.S. corporate tax reform.

As previously disclosed, we received a RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. 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 3, 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):

	June 30, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 21,758	$ 29,304
Total assets	$ 59,373	$ 66,416
Current portion of long-term debt	$ 2,816	$ 4,419
Long-term debt	$ 27,798	$ 29,510
Stockholders' equity	$ 10,794	$ 12,500

Cash, cash equivalents and marketable securities

We have global access to our $21.8 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.

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 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 June 7, 2019 and March 8, 2019, respectively, an increase of 10% over the quarterly cash dividend paid in each quarter of 2018.

We have also returned capital to stockholders through our stock repurchase program. During the six months ended June 30, 2019, we repurchased $5.4 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 June 30, 2019, $4.7 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 June 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 June 30, 2019.

Cash flows

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

	Six months ended June 30,	
	2019	2018
Net cash provided by operating activities	$ 3,259	$ 4,829
Net cash provided by investing activities	$ 6,300	$ 17,844
Net cash used in financing activities	$ (10,979)	$ (16,342)

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 six months ended June 30, 2019, decreased compared with the same period in the prior year due primarily to an increase in payments to the IRS related to an advance deposit, an increase in sales deductions paid to customers and lower net income.

Investing

Cash provided by investing activities during the six months ended June 30, 2019 and 2018, was due primarily to net cash inflows related to marketable securities of $6.6 billion and $18.0 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 six months ended June 30, 2019 and 2018, were $260 million and $342 million, respectively. We currently estimate 2019 spending on capital projects to be approximately $700 million.

Financing

Cash used in financing activities during the six months ended June 30, 2019, was due primarily to repurchases of our common stock of $5.4 billion, repayment of debt of $3.7 billion and payment of dividends of $1.8 billion. Cash used in financing activities during the six months ended June 30, 2018, was due primarily to repurchases of our common stock of $13.9 billion, repayment of debt of $0.5 billion and payment of dividends of $1.8 billion. See Note 9, Financing arrangements, and Note 10, Stockholders’ equity, to the condensed consolidated financial statements for further discussion.

Critical accounting policies

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

Management determined that, as of June 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 13, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Report 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. We have described in our Annual Report on Form 10-K for the year ended December 31, 2018, the primary risks related to our business, and we periodically update those risks for material developments. Those risks are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Below, we are providing, in supplemental form, the material changes to our risk factors that occurred during the past quarter. Our risk factors disclosed in Part I, Item 1A, of our Annual Report, on Form 10-K for the year ended December 31, 2018, provide additional disclosure for these supplemental risks and are incorporated herein by reference.

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

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

—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 Democrats took control of the U.S. House of Representatives following the November 2018 election. Recent proposed legislation has been introduced in Congress 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 significantly change the way Medicare reimburses for drugs in Medicare Part B. In addition, 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. A number of other Congressional committees have also held hearings during the first half of 2019 on drug pricing.

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, in May 2018, the U.S. presidential administration (the Administration) released a drug pricing "blueprint" and requested public comment on an array of policy ideas intended to increase competition, improve the negotiating power of the federal government, reduce drug prices and lower patient out-of-pocket costs. This blueprint includes a number of policy ideas with the potential to significantly impact, whether individually or collectively, our industry. Such proposals 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 that time, the president and/or federal agencies, such as the Centers for Medicare and Medicaid Services (CMS), have announced a number of demonstration projects, recommendations and proposals to implement various elements described in the drug pricing blueprint. CMS, the federal agency responsible for administering Medicare and overseeing state Medicaid programs and Health Insurance Marketplaces, 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 October 2018, President Trump announced that CMS was evaluating a pilot program proposed to initially cover fifty percent of spending on Part B single-source drugs referred to as the "International Price Index" (IPI) model that would, among other things, set the Medicare payment amount for such single-source drugs to more closely align with international drug prices. 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 in the United States. 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 such plan will cover another therapy and proposing lower reimbursement rates for new Part B drugs. Some of the efforts of CMS and the U.S. Department of Health and Human Services (HHS, the federal agency of which CMS is a part) to implement elements of the drug pricing blueprint have not ultimately resulted in policy changes. For example, in July 2019 Administration officials announced the withdrawal of a proposed HHS rule that would have excluded from federal anti-kickback safe harbor protection certain rebates paid to PBMs under Medicare. However, following the withdrawal of this rebate rule, the Administration might pursue the IPI model or other drug pricing initiatives.

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 state reimbursement and pricing actions 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 requiring notices to a state agency of certain price increases. Other states are seeking to change the way their states 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 PBMs to eliminate the drug purchasing model in which PBMs bill the state more than they reimburse pharmacists for filling Medicaid patient prescriptions. In January 2019, California's governor issued an executive order expanding state Medicaid coverage and directing state agencies and programs to consolidate drug purchases and to negotiate drug prices with manufacturers. Additionally, four states have enacted laws to facilitate the importation of drugs from Canada. These state importation programs must first be approved by HHS 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 and their respective members' 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 will likely continue to seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage, particularly in treatment areas where the payer has taken the position that multiple branded products are therapeutically comparable. Payers also control costs by imposing restrictions on access to or usage of our products, such as requiring that patients first try a drug preferred by the payer or 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 proprotein convertase subtilisin/kexin type 9 (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®.

Significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. For example, in the United States, the top three PBMs now oversee 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. 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.

We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.

The global supply of our products and product candidates for commercial sales and for use in our clinical trials is significantly dependent on the uninterrupted and efficient operation of our manufacturing facilities, in particular those in the U.S. territory of Puerto Rico and Thousand Oaks, California. See our Annual Report on Form 10-K for the year ended December 31, 2018, Part I, Item 1A. Risk Factors—*Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

We currently perform a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California. A substantial disruption in our ability to operate our Thousand Oaks, California manufacturing facility could materially and adversely affect our ability to supply our product candidates for use in our clinical trials, leading to delays in development of our product candidates.

In addition, we currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico. In late September 2017, Hurricane Maria made landfall on the island of Puerto Rico. The hurricane destroyed residential and commercial buildings, agriculture, communications networks and most of Puerto Rico's electric grid. While the critical manufacturing areas of our commercial manufacturing facility were not significantly impacted by the storm, the restoration of electrical service on the island was a slow process, and our facility operated with electrical power from back-up diesel powered generators for some time. In January 2018, we reconnected to the Puerto Rico electric grid but have continued to use diesel generators as needed when sufficient electric power has not been reliably available. Further instability of the electric grid could require us to increase the use of our generators or even return to using them exclusively. In addition, future storms or other disasters or events could cause a more significant impact to our manufacturing operations. Also, there is political instability in the Puerto Rican government that has led to civil unrest and the recent resignation of the governor. While our ability to manufacture and supply our products has not, to date, been impacted by the political instability, any substantial disruption in our ability to operate our Puerto Rico manufacturing facility (whether due to problems with the facility itself, compliance with regulatory requirements, the infrastructure and services available on the island, the unavailability of raw materials or supplies from vendors, the unavailability of key staff or otherwise) or get supplies and manufactured products transported to and from that location could materially and adversely affect our ability to supply our products and affect our product sales. See our Annual Report on Form 10-K for the year ended December 31, 2018, Part I, Item 1A. Risk Factors—*Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

The impact of Hurricane Maria and the political instability in Puerto Rico have placed greater stress on the island's already challenged economy. Prior to Hurricane Maria, the government of Puerto Rico was unable to pay its roughly $72 billion in debt. In June 2016, the U.S. Congress passed the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA), which established a Financial Oversight and Management Board (Oversight Board) to provide fiscal oversight through the development and approval of fiscal plans and budgets for Puerto Rico and to assist in its debt restructuring. In May 2017, after negotiations for debt restructuring with creditors were unsuccessful, the Oversight Board approved and certified the filing in the U.S. District Court for the District of Puerto Rico of a voluntary petition under Title III of PROMESA for the government of Puerto Rico and certain of its governmental entities, including the Puerto Rico Electric Power Authority (PREPA). Title III of PROMESA provides Puerto Rico with a judicial process for restructuring its debt similar to, but not identical to, Chapter 9 of the U.S. Bankruptcy Code. The governor of Puerto Rico declared a state of emergency and authorized a moratorium on the payment of general obligation bonds and other debts issued by certain instrumentalities, which moratorium has been extended and may continue to be extended while the Oversight Board is in effect. Given the severe conditions in Puerto Rico after Hurricane Maria, resolution of Puerto Rico's debt situation through the PROMESA judicial process has been delayed. In the case of PREPA, the effects of Hurricane Maria and several changes in PREPA's management have delayed reconstruction efforts.

In June 2018, the Oversight Board certified a budget for Puerto Rico's fiscal year 2019 that imposes significant expense reductions across the government. The Title III Court dismissed most of the government's challenges to the budget, and the governor and legislature of Puerto Rico filed appeals before the U.S. Court of Appeals for the First Circuit (First Circuit Court). In February 2019, the First Circuit Court affirmed the Title III Court's dismissal of the legislature's appeal; however, the governor's appeal is still pending before the First Circuit Court.

In addition, certain non-governmental entities have brought suit claiming the appointment process of the Oversight Board members set forth in PROMESA conflicts with the appointments clause of the U.S. Constitution. In February 2019, the First Circuit Court ruled that the appointment was unconstitutional and in June 2019, the U.S. Supreme Court accepted the case for review. If the U.S. Supreme Court were to hold that PROMESA has a constitutional infirmity and that actions taken by the Oversight Board are invalid, the commencement of all Title III proceedings could be invalid. In such event, the current debt restructuring process and the debtholder litigation stay under Title III of PROMESA could be in jeopardy.

In October 2018, the fiscal plan for Puerto Rico was updated, including a projected increase in federal disaster funding and projected material deficits once the stimulus effects of the disaster recovery dissipate. The fiscal plan stresses the importance of structural reforms to address Puerto Rico's challenging economic and demographic trends that may be difficult to implement as well as have a material adverse impact on our consolidated financial statements.

In May 2019, the fiscal plan was further updated to incorporate a revised projection on federal disaster spending. The new fiscal plan projects a smaller surplus in the short-term due to a longer rollout in federal disaster assistance. In June 2019, the Oversight Board certified the fiscal year 2020 budget, which is higher than the 2019 budget.

In addition, the Tax Cuts and Jobs Act (2017 Tax Act) will no longer permit deferral of U.S. taxation on Puerto Rico earnings of U.S. companies (or their foreign subsidiaries), although these earnings generally will be taxed in the United States at a reduced 10.5% rate. Given Puerto Rico's challenged economy and hurricane recovery needs, it may be difficult for Puerto Rico to sustain or grow its manufacturing base due to competition from other foreign locations subject to a similar level of U.S. taxation, or U.S. locations due to the reduction in the U.S. corporate tax rate from 35% to 21%. The manufacturing sector contributes more than 45% of Puerto Rico's gross domestic product, and multinational companies with Puerto Rico operations contribute approximately 30% of Puerto Rico's revenue base.

While PROMESA and the actions above continue to be important factors in moving Puerto Rico toward economic stability, there is still a risk that Puerto Rico's ongoing economic challenges, the effects of Hurricane Maria and the potential impact of the 2017 Tax Act could negatively affect the territorial government's provision of utilities or other services in Puerto Rico that we use in the operation of our business, create the potential for increased taxes or fees to operate in Puerto Rico, result in a migration of workers from Puerto Rico to the mainland United States, or make it more expensive or difficult for us to operate in Puerto Rico. In addition, the political instability in Puerto Rico described above may cause additional disruption and further delay the resolution of Puerto Rico's debt restructuring and economic recovery. These factors could materially and adversely affect our ability to supply our products and affect our product sales.

A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems and network-connected control systems and our data, interrupt the operation of our business and affect our reputation.

To achieve our business objectives, we rely to a large extent upon sophisticated information technology systems and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or affect our reputation.

Our information technology systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. The complexity and interconnected nature of our systems makes them potentially vulnerable to breakdown or other service interruptions. Our systems are also subject to frequent cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Such attacks could include the use of harmful and virulent malware, including ransomware or other denials of service, and can be deployed through various means including the software supply chain, e-mail, malicious websites, and the use of social engineering. Attacks such as those seen with other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access important data needed to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and/or distributing our products. For example, in 2017, a pharmaceutical company experienced a cyberattack involving virulent malware that significantly disrupted its operations, including its research and sales operations and the production of some of its medicines and vaccines. As a result of the cyberattack, its orders and sales for certain products in certain markets were negatively impacted. Our systems also contain and utilize a high volume of sensitive data, including intellectual property, trade secrets, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials and/or personal information belonging to us, our staff, our patients, customers and/or other parties. In some cases, we utilize third-party service providers to process, store, manage or transmit such data, which may increase our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) or lapses by employees, service providers, nation states, organized crime organizations, “hacktivists” or others, create risks that our sensitive data may be exposed to unauthorized persons, our competitors, or the public. Finally, domestic and global government regulators, our business partners, suppliers with whom we do business, companies that provide us or our partners with business services and companies we may acquire may face similar risks, and security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. For example, in June 2019, a vendor that performs a variety of tests and analytical services that we and other biopharmaceutical companies use in developing and manufacturing our products experienced a cyberattack requiring us to disconnect our systems from the vendor’s systems. While we were able to reconnect our systems after several weeks, an extended service outage impacting this or other vendors, particularly where such vendor is the single source from which we obtain the services, could have a material adverse effect on our business or results of operations. In addition, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers.

Although we have experienced system breakdowns, attacks and information security breaches, we do not believe such breakdowns, attacks and breaches have had a material adverse effect on our business or results of operations. We continue to invest in the monitoring, protection, and resilience of our critical or sensitive data and systems. However, there can be no assurance that our efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks, or breaches of our systems that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in financial, legal, business or reputational harm to us or impact our stock price. While we maintain cyber-liability insurance, our insurance is not sufficient to cover us against all losses that could potentially result from a service interruption, breach of our systems or loss of our critical or sensitive data.

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

During the three months ended June 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]
April 1 - 30	5,910,200	$ 186.39	5,910,200	$ 981,408,982
May 1 - 31	4,457,100	$ 170.96	4,457,100	$ 5,219,445,027
June 1 - 30	2,718,800	$ 178.60	2,718,800	$ 4,733,865,620
Total	13,086,100	$ 179.51	13,086,100	

(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
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).
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	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*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

(* = filed herewith)

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

(+ = management contract or compensatory plan or arrangement)

SIGNATURES

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

Amgen Inc.
(Registrant)

Date: July 30, 2019

By: /s/ DAVID W. MELINE

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

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. SUCH EXCLUDED INFORMATION HAS BEEN MARKED WITH "[***]".

June 25, 2019

Via facsimile and overnight courier

UCB Celltech
(as successor in interest to Celltech R&D Limited)
208 Bath Road
Slough SL1 3WE
Berkshire, England
Attention: Company Secretary

Re: Romosozumab

Dear Sirs:

UCB Celltech, as successor in interest to Celltech R&D Limited ("**UCB**") and Amgen Inc. ("**Amgen**" and, together with UCB, the "**Parties**") entered into that certain Collaboration and Licence Agreement effective May 10, 2002, as amended by Amendment No. 1 to the Agreement, effective June 9, 2003 and Amendment No. 2 to the Agreement, effective November 14, 2016 (as amended, the "**Agreement**"). The Parties, by entering into this letter agreement (this "Letter Agreement"), agree as set forth below. Capitalized terms used but not defined herein have the meanings ascribed to them in the Agreement, as amended.

In order to align the Parties' interests to ensure a successful [***] launch period, and notwithstanding the principles for calculating the Detail Cost set forth in Schedule C of the Agreement, the Parties hereby agree that, on an exceptional basis, for a period of [***] after First Commercial Sale in [***], Amgen will allocate an amount equal to [***] of its Sales Force Costs for Primary Details in [***] (the "Incremental Launch Amount"), which amount shall be charged to the Product Contribution. For the avoidance of doubt, (i) the Incremental Launch Amount shall be in addition to the amounts allocated and charged to the Product Contribution in accordance with Schedule C of the Agreement, and, (ii) at the end of [***], the charging of the Incremental Launch Amount to the Product Contribution shall cease and thereafter Amgen shall allocate and charge to the Product Contribution only those amounts calculated in accordance with the principles set forth in Schedule C of the Agreement.

Notwithstanding the principles for calculating the Detail Cost set forth in Schedule C of the Agreement, the Parties hereby agree that (i) for a period of [***] after First Commercial Sale in [***], Amgen will allocate [***] of its Sales Force Costs for all details in [***] and UCB will allocate [***] of its Sales Force Costs for all details in [***], which amounts shall be charged to the Product Contribution, provided, that from and after the end of such [***] period, the allocation of Sales Force Costs in [***] shall be calculated and charged to the Product Contribution in accordance with the principles set forth in Schedule C of the Agreement and (ii) all costs in [***] will be shared [***] by the parties and charged to the Product Contribution.

Each of Amgen and UCB represents and warrants that it has the right to enter into this Letter Agreement and that the terms of this Letter Agreement are not inconsistent with other contractual obligations (express or implied) that it may have. No amendment, modification or supplement of any provision of this Letter Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party. This Letter Agreement shall be governed and interpreted in all respects under the substantive laws of the State of New York, as applied to agreements executed and performed entirely in the State of New York by residents of the State of New York, without regard to the United Nations Convention on International Contracts for the Sale of Goods or conflicts of law principles.

This Letter Agreement may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Signature pages of this Letter Agreement may be exchanged by facsimile or other electronic means without affecting the validity thereof. If this Letter Agreement is acceptable to you, please confirm by signing and returning a copy to Amgen, whereupon this Letter Agreement shall become a binding agreement between us.

Yours sincerely,

AMGEN INC.

/s/ Murdo Gordon

By: Murdo Gordon
Title: EVP, Global Commercial Operations

/s/ David W. Meline

By: David W. Meline
Title: EVP, Chief Financial Officer

Acknowledged and agreed:

UCB CELLTECH

/s/ Mark Glyn Hardy

By: Mark Glyn Hardy
Title: Company Secretary

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: July 30, 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: July 30, 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 ended June 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: July 30, 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 ended June 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: July 30, 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.