

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2020

or

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

Commission File Number: 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

95-3540776

(I.R.S. Employer
Identification No.)

One Amgen Center Drive

Thousand Oaks

California

(Address of principal executive offices)

91320-1799

(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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

No

As of October 23, 2020, the registrant had 582,168,612 shares of common stock, \$0.0001 par value, outstanding.

AMGEN INC.

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PART I — FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Revenues:				
Product sales	\$ 6,104	\$ 5,463	\$ 17,906	\$ 16,323
Other revenues	319	274	884	842
Total revenues	<u>6,423</u>	<u>5,737</u>	<u>18,790</u>	<u>17,165</u>
Operating expenses:				
Cost of sales	1,561	1,036	4,562	3,103
Research and development	1,062	1,001	2,978	2,804
Selling, general and administrative	1,346	1,223	3,957	3,637
Other	1	1	162	(5)
Total operating expenses	<u>3,970</u>	<u>3,261</u>	<u>11,659</u>	<u>9,539</u>
Operating income	2,453	2,476	7,131	7,626
Interest expense, net	302	313	944	988
Interest and other income, net	55	114	69	517
Income before income taxes	2,206	2,277	6,256	7,155
Provision for income taxes	185	309	607	1,016
Net income	<u>\$ 2,021</u>	<u>\$ 1,968</u>	<u>\$ 5,649</u>	<u>\$ 6,139</u>
Earnings per share:				
Basic	\$ 3.45	\$ 3.29	\$ 9.61	\$ 10.08
Diluted	\$ 3.43	\$ 3.27	\$ 9.54	\$ 10.01
Shares used in calculation of earnings per share:				
Basic	585	599	588	609
Diluted	589	602	592	613

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Net income	\$ 2,021	\$ 1,968	\$ 5,649	\$ 6,139
Other comprehensive (loss) income, net of reclassification adjustments and taxes:				
Gains (losses) on foreign currency translation	14	(39)	(41)	(56)
(Losses) gains on cash flow hedges	(128)	86	(305)	27
Gains (losses) on available-for-sale securities	1	30	(20)	404
Other	(7)	—	(9)	6
Other comprehensive (loss) income, net of taxes	(120)	77	(375)	381
Comprehensive income	<u>\$ 1,901</u>	<u>\$ 2,045</u>	<u>\$ 5,274</u>	<u>\$ 6,520</u>

See accompanying notes.

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

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,087	\$ 6,037
Marketable securities	3,273	2,874
Trade receivables, net	4,094	4,057
Inventories	3,942	3,584
Other current assets	2,265	1,888
Total current assets	<u>22,661</u>	<u>18,440</u>
Property, plant and equipment, net	4,816	4,928
Intangible assets, net	17,254	19,413
Goodwill	14,674	14,703
Other assets	5,232	2,223
Total assets	<u>\$ 64,637</u>	<u>\$ 59,707</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,161	\$ 1,371
Accrued liabilities	8,701	8,511
Current portion of long-term debt	91	2,953
Total current liabilities	<u>9,953</u>	<u>12,835</u>
Long-term debt	34,196	26,950
Long-term deferred tax liabilities	210	606
Long-term tax liabilities	7,560	8,037
Other noncurrent liabilities	1,759	1,606
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; \$0.0001 par value; 2,750.0 shares authorized; outstanding — 583.5 shares in 2020 and 591.4 shares in 2019	31,713	31,531
Accumulated deficit	(19,851)	(21,330)
Accumulated other comprehensive loss	(903)	(528)
Total stockholders' equity	<u>10,959</u>	<u>9,673</u>
Total liabilities and stockholders' equity	<u>\$ 64,637</u>	<u>\$ 59,707</u>

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, 2019	591.4	\$ 31,531	\$ (21,330)	\$ (528)	\$ 9,673
Cumulative effect of changes in accounting principles, net of tax	—	—	(2)	—	(2)
Net income	—	—	1,825	—	1,825
Other comprehensive loss, net of taxes	—	—	—	(134)	(134)
Dividends declared on common stock (\$1.60 per share)	—	—	(938)	—	(938)
Issuance of common stock in connection with the Company's equity award programs	0.9	10	—	—	10
Stock-based compensation expense	—	52	—	—	52
Tax impact related to employee stock-based compensation expense	—	(68)	—	—	(68)
Repurchases of common stock	(4.3)	—	(933)	—	(933)
Balance as of March 31, 2020	588.0	31,525	(21,378)	(662)	9,485
Net income	—	—	1,803	—	1,803
Other comprehensive loss, net of taxes	—	—	—	(121)	(121)
Issuance of common stock in connection with the Company's equity award programs	1.0	65	—	—	65
Stock-based compensation expense	—	101	—	—	101
Tax impact related to employee stock-based compensation expense	—	(81)	—	—	(81)
Repurchases of common stock	(2.6)	—	(591)	—	(591)
Other	—	—	(2)	—	(2)
Balance as of June 30, 2020	586.4	31,610	(20,168)	(783)	10,659
Net income	—	—	2,021	—	2,021
Other comprehensive loss, net of taxes	—	—	—	(120)	(120)
Dividends declared on common stock (\$1.60 per share)	—	—	(952)	—	(952)
Issuance of common stock in connection with the Company's equity award programs	0.1	5	—	—	5
Stock-based compensation expense	—	109	—	—	109
Tax impact related to employee stock-based compensation expense	—	(11)	—	—	(11)
Repurchases of common stock	(3.0)	—	(752)	—	(752)
Balance as of September 30, 2020	583.5	\$ 31,713	\$ (19,851)	\$ (903)	\$ 10,959

See accompanying notes.

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

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

See accompanying notes.

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

	Nine months ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net income	\$ 5,649	\$ 6,139
Depreciation, amortization and other	2,728	1,504
Deferred income taxes	(339)	(172)
Other items, net	270	169
Changes in operating assets and liabilities, net of acquisition:		
Trade receivables, net	(31)	(63)
Inventories	(316)	(101)
Other assets	64	(269)
Accounts payable	(202)	(196)
Accrued income taxes, net	(301)	(128)
Long-term tax liabilities	110	(262)
Other liabilities	712	15
Net cash provided by operating activities	8,344	6,636
Cash flows from investing activities:		
Purchases of marketable securities	(5,329)	(9,062)
Proceeds from sales of marketable securities	2,597	3,019
Proceeds from maturities of marketable securities	2,338	18,441
Purchases of property, plant and equipment	(435)	(430)
Purchases of equity method investments	(3,154)	(14)
Other	(34)	(282)
Net cash (used in) provided by investing activities	(4,017)	11,672
Cash flows from financing activities:		
Net proceeds from issuance of debt	8,914	—
Repayment of debt	(5,000)	(4,514)
Repurchases of common stock	(2,281)	(6,608)
Dividends paid	(2,823)	(2,649)
Other	(87)	(67)
Net cash used in financing activities	(1,277)	(13,838)
Increase in cash and cash equivalents	3,050	4,470
Cash and cash equivalents at beginning of period	6,037	6,945
Cash and cash equivalents at end of period	\$ 9,087	\$ 11,415

See accompanying notes.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2020
(Unaudited)

1. Summary of significant accounting policies

Business

Amgen Inc. (including its subsidiaries, referred to as “Amgen,” “the Company,” “we,” “our” or “us”) is a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. We operate in one business segment: human therapeutics.

Basis of presentation

The financial information for the three and nine months ended September 30, 2020 and 2019, 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, 2019, and with our condensed consolidated financial statements and the notes thereto contained in our Quarterly Report on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020.

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 \$8.8 billion and \$8.4 billion as of September 30, 2020 and December 31, 2019, respectively.

Equity method investments

The equity method of accounting is used for equity investments that give us the ability to exert significant influence, but not control, over an investee based on such factors as our ownership percentage, voting and other shareholder rights, board of director representation and the existence of other collaborative or business relationships. The equity method of accounting requires us to allocate the difference between the fair value of securities acquired and our proportionate share of the carrying value of the underlying assets (the basis difference) to various items and amortize such differences over their useful lives. Our share of the investees’ earnings or losses and amortization of basis differences, if any, are recorded one quarter in arrears in Interest and other income, net, in the Condensed Consolidated Statements of Income.

We record impairment losses on our equity method investments if we deem the impairment to be other-than-temporary. We deem an impairment to be other-than-temporary based on various factors including, but not limited to, the length of time the fair value is below the carrying value, volatility of the security price and our intent and ability to retain the investment to allow for a recovery in fair value.

Recent accounting pronouncements

In June 2016, the Financial Accounting Standards Board (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 are now presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the former other-than-temporary-impairment model. We adopted this standard as of January 1, 2020, using a modified-retrospective approach. Adoption of the standard did not have a material impact on our condensed consolidated financial statements.

In March 2020, the FASB issued a new accounting standard to ease the financial reporting burdens of the expected market transition from the London Interbank Offered Rate (LIBOR) and other interbank offered rates to alternative reference rates, commonly referred to as reference rate reform. The new standard provides temporary optional expedients and exceptions to current GAAP guidance on contract modifications and hedge accounting. Specifically, a modification to transition to an alternative reference rate is treated as an event that does not require contract remeasurement or reassessment of a previous accounting treatment. Moreover, for all types of hedging relationships, an entity may change the reference rate without having to dedesignate the hedging relationship. The standard is generally effective for all contract modifications made and hedging relationships evaluated through December 31, 2022. 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. The majority of rest-of-world (ROW) revenues relates to products sold in Europe.

Revenues were as follows (in millions):

	Three months ended September 30,					
	2020			2019		
	U.S.	ROW	Total	U.S.	ROW	Total
Enbrel® (etanercept)	\$ 1,289	\$ 36	\$ 1,325	\$ 1,323	\$ 43	\$ 1,366
Prolia® (denosumab)	478	223	701	425	205	630
Neulasta® (pegfilgrastim)	484	71	555	619	92	711
Otezla® (apremilast)	439	99	538	—	—	—
XGEVA® (denosumab)	363	118	481	356	120	476
Aranesp® (darbepoetin alfa)	158	226	384	204	248	452
KYPROLIS® (carfilzomib)	173	87	260	163	103	266
Repatha® (evolocumab)	92	113	205	85	83	168
Other products	1,142	513	1,655	854	540	1,394
Total product sales ⁽¹⁾	\$ 4,618	\$ 1,486	6,104	\$ 4,029	\$ 1,434	5,463
Other revenues			319			274
Total revenues			\$ 6,423			\$ 5,737

	Nine months ended September 30,					
	2020			2019		
	U.S.	ROW	Total	U.S.	ROW	Total
ENBREL	\$ 3,619	\$ 105	\$ 3,724	\$ 3,744	\$ 136	\$ 3,880
Prolia®	1,341	673	2,014	1,273	647	1,920
Neulasta®	1,538	219	1,757	2,231	325	2,556
Otezla®	1,280	298	1,578	—	—	—
XGEVA®	1,036	361	1,397	1,091	355	1,446
Aranesp®	489	704	1,193	578	724	1,302
KYPROLIS®	527	266	793	483	295	778
Repatha®	331	303	634	259	202	461
Other products	3,164	1,652	4,816	2,503	1,477	3,980
Total product sales ⁽¹⁾	\$ 13,325	\$ 4,581	17,906	\$ 12,162	\$ 4,161	16,323
Other revenues			884			842
Total revenues			\$ 18,790			\$ 17,165

⁽¹⁾ Hedging gains and losses, which are included in product sales, were not material for the three and nine months ended September 30, 2020 and 2019.

3. Income taxes

The effective tax rates for the three and nine months ended September 30, 2020, were 8.4% and 9.7%, respectively, compared with 13.6% and 14.2%, respectively, for the corresponding periods of the prior year.

The decrease in our effective tax rates for the three and nine months ended September 30, 2020, was primarily due to favorable items in the quarter, including effective settlement of certain federal income tax matters and adjustments to prior year tax liabilities, partially offset by changes in jurisdictional mix of earnings. The tax rate for the nine months ended September 30, 2020 was also favorably affected by amortization related to the Otezla[®] acquisition. 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 are subject to tax incentive grants through 2035. In addition, the Company's operations conducted in Singapore are subject to a tax incentive grant through 2034. These earnings are also subject to U.S. tax at a reduced rate of 10.5%.

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

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes may arise with tax authorities involving issues regarding the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and relevant facts. In April 2017, we received a Revenue Agent Report (RAR) from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012. The RAR proposed to make significant adjustments that primarily relate 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 calculations but continues to propose substantial adjustments. We disagree with the proposed adjustments and calculations, and the matter is currently within the jurisdiction of the IRS administrative appeals office. If unable to reach resolution, we will vigorously contest the proposed adjustments through the judicial process. In addition, in May 2020, we received an RAR from the IRS for the years 2013, 2014 and 2015 proposing adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. In September 2020, we received a revised RAR that continues to propose substantial adjustments for the years 2013, 2014 and 2015. We disagree with the proposed adjustments and calculations and will pursue resolution with the IRS administrative appeals office. We are also currently under examination by a number of other state and foreign tax jurisdictions.

Final resolution of these complex matters 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 substantially 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.

During the three and nine months ended September 30, 2020, the gross amounts of our unrecognized tax benefits (UTBs) increased \$65 million and \$170 million, respectively, as a result of tax positions taken during the current year. Substantially all of the UTBs as of September 30, 2020, 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 primarily include shares that may be issued under our stock option, restricted stock and performance unit award programs (collectively, dilutive securities), as determined by using the treasury stock method.

The computations for basic and diluted EPS were as follows (in millions, except per-share data):

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Income (Numerator):				
Net income for basic and diluted EPS	\$ 2,021	\$ 1,968	\$ 5,649	\$ 6,139
Shares (Denominator):				
Weighted-average shares for basic EPS	585	599	588	609
Effect of dilutive securities	4	3	4	4
Weighted-average shares for diluted EPS	589	602	592	613
Basic EPS	\$ 3.45	\$ 3.29	\$ 9.61	\$ 10.08
Diluted EPS	\$ 3.43	\$ 3.27	\$ 9.54	\$ 10.01

For the three and nine months ended September 30, 2020 and 2019, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

5. Collaborations

On January 2, 2020, we closed our strategic collaboration with BeiGene, Ltd. (BeiGene) to expand our oncology presence in China. Under the collaboration, BeiGene commenced selling XGEVA[®] and will commercialize KYPROLIS[®] and BLINCYTO[®] (blinatumomab) in China, and Amgen will share profits and losses equally during the initial product-specific commercialization periods; thereafter, product rights may revert to Amgen, and Amgen will pay royalties to BeiGene on sales in China.

In addition, we will jointly develop a portion of our oncology portfolio with BeiGene sharing in global research and development (R&D) costs by providing cash and development services up to \$1.25 billion. Upon regulatory approval, BeiGene will assume commercialization rights in China for a specified period, and Amgen and BeiGene will share profits equally until certain of these product rights revert to Amgen. Upon return of the product rights, Amgen will pay royalties to BeiGene on sales in China for a specified period. For product sales outside of China, Amgen will also pay BeiGene royalties.

For the three and nine months ended September 30, 2020, net costs recovered from BeiGene for oncology product candidates were \$57 million and \$169 million, respectively, and were recorded as an offset to R&D expense in the Condensed Consolidated Statements of Income. Profit share payments and product sales between Amgen and BeiGene were not material for the three and nine months ended September 30, 2020. As of September 30, 2020, the amount owed from BeiGene for net costs recovered was \$112 million, which is included in Other current assets in the Condensed Consolidated Balance Sheets. In connection with this collaboration, we acquired an ownership interest in BeiGene. See Note 6, Investments.

6. Investments

Available-for-sale investments

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

Types of securities as of September 30, 2020	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	\$ 172	\$ 2	\$ —	\$ 174
U.S. Treasury bills	6,399	—	—	6,399
Corporate debt securities:				
Financial	—	—	—	—
Industrial	—	—	—	—
Other	—	—	—	—
Residential-mortgage-backed securities	—	—	—	—
Money market mutual funds	5,016	—	—	5,016
Other short-term interest-bearing securities	—	—	—	—
Total interest-bearing securities	<u>\$ 11,587</u>	<u>\$ 2</u>	<u>\$ —</u>	<u>\$ 11,589</u>

Types of securities as of December 31, 2019	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	\$ 359	\$ 1	\$ —	\$ 360
U.S. Treasury bills	—	—	—	—
Corporate debt securities:				
Financial	1,108	13	—	1,121
Industrial	824	10	—	834
Other	195	3	—	198
Residential-mortgage-backed securities	181	1	—	182
Money market mutual funds	5,250	—	—	5,250
Other short-term interest-bearing securities	289	—	—	289
Total interest-bearing securities	<u>\$ 8,206</u>	<u>\$ 28</u>	<u>\$ —</u>	<u>\$ 8,234</u>

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

Condensed Consolidated Balance Sheets locations	September 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 8,316	\$ 5,360
Marketable securities	3,273	2,874
Total interest-bearing securities	<u>\$ 11,589</u>	<u>\$ 8,234</u>

Cash and cash equivalents in the above table excludes bank account cash of \$771 million and \$677 million as of September 30, 2020 and December 31, 2019, respectively.

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

Contractual maturities	September 30, 2020	December 31, 2019
Maturing in one year or less	\$ 11,536	\$ 5,629
Maturing after one year through three years	53	2,304
Maturing after three years through five years	—	119
Residential-mortgage-backed securities	—	182
Total interest-bearing securities	<u>\$ 11,589</u>	<u>\$ 8,234</u>

For the three months ended September 30, 2020, realized gains and losses on interest-bearing securities were not material. For the three months ended September 30, 2019, realized gains and losses on interest-bearing securities were \$21 million and \$24 million, respectively. For the nine months ended September 30, 2020 and 2019, realized gains on interest-bearing securities were \$37 million and \$23 million, respectively, and realized losses on interest-bearing securities were \$4 million and \$32 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 primary objective of our investment portfolio is to maintain 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 primarily issued by institutions with investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

Equity securities

We held investments in equity securities with readily determinable fair values (publicly traded securities) of \$376 million and \$303 million as of September 30, 2020 and December 31, 2019, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. For the three months ended September 30, 2020 and 2019, unrealized gains and losses on publicly traded securities were a net gain of \$60 million and a net loss of \$15 million, respectively. For the nine months ended September 30, 2020 and 2019, unrealized gains and losses on publicly traded securities were net gains of \$65 million and \$42 million, respectively. Realized gains and losses on publicly traded securities for the three and nine months ended September 30, 2020 and 2019, were not material.

We held investments of \$170 million and \$176 million in equity securities without readily determinable fair values as of September 30, 2020 and December 31, 2019, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. Gains and losses recognized on these securities, including adjustments to the carrying values of these securities, were not material for the three and nine months ended September 30, 2020 and 2019.

Equity method investments

Limited partnerships

We held limited partnership investments of \$366 million and \$320 million as of September 30, 2020 and December 31, 2019, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. These investments, primarily investment funds of early-stage biotechnology companies, are accounted for by using the equity method of accounting and are measured by using our proportionate share of the net asset values of the underlying investments held by the limited partnerships as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of September 30, 2020, unfunded additional commitments to be made for these investments during the next several years were not material. For the three months ended September 30, 2020 and 2019, net gains recognized from our limited partnership investments were \$63 million and \$5 million, respectively. For the nine months ended September 30, 2020 and 2019, net gains recognized from our limited partnership investments were \$73 million and \$29 million, respectively.

BeiGene

On January 2, 2020, we acquired a 20.5% ownership interest in BeiGene for \$2.8 billion, of which \$2.6 billion was attributed to the fair value of equity securities upon closing, with the remainder attributed to prepaid R&D. Our equity investment in BeiGene is included in Other assets in the Condensed Consolidated Balance Sheets. The fair value of equity securities acquired exceeded our proportionate share of the carrying value of the underlying net assets of BeiGene by approximately \$2.4 billion. This investment is accounted for by using the equity method of accounting, which requires us to identify and allocate amounts to the items that give rise to the basis difference and to amortize these items over their useful lives. This amortization, along with our share of the results of operations of BeiGene, are included in Interest and other income, net, in our Condensed Consolidated Statements of Income. Recognition occurs one quarter in arrears, which began in the second quarter of 2020. The basis difference was allocated to finite-lived intangible assets, indefinite-lived intangible assets, equity-method goodwill and related deferred taxes. The finite-lived intangible assets are being amortized over a period ranging from 8 to 15 years.

During the three and nine months ended September 30, 2020, we recognized an increase in the carrying value of our investment by purchasing additional shares to maintain our ownership interest for an aggregate cost of \$505 million and recognized \$23 million for the impact of other BeiGene ownership transactions. The carrying value of the investment during the three and nine months ended September 30, 2020, was reduced for our share of BeiGene's net losses of \$68 million and \$143 million, respectively, and amortization of the basis difference of \$36 million and \$72 million, respectively.

As of September 30, 2020, the carrying and fair values of our approximately 20.4% ownership interest in BeiGene totaled \$3.0 billion and \$5.3 billion, respectively. As of September 30, 2020, we believe the carrying value of our equity investment in BeiGene is fully recoverable. See Note 1, Summary of significant accounting policies, for factors considered in determining our conclusion. For information on a collaboration agreement we entered into with BeiGene in connection with this investment, see Note 5, Collaborations.

7. Inventories

Inventories consisted of the following (in millions):

	September 30, 2020	December 31, 2019
Raw materials	\$ 496	\$ 358
Work in process	2,551	2,227
Finished goods	895	999
Total inventories	<u>\$ 3,942</u>	<u>\$ 3,584</u>

8. Goodwill and other intangible assets

Goodwill

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

	Nine months ended September 30, 2020
Beginning balance	\$ 14,703
Currency translation adjustment	(29)
Ending balance	<u>\$ 14,674</u>

Other intangible assets

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

	September 30, 2020			December 31, 2019		
	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	\$ 25,572	\$ (9,998)	\$ 15,574	\$ 25,575	\$ (8,322)	\$ 17,253
Licensing rights	3,747	(2,710)	1,037	3,761	(2,398)	1,363
Marketing-related rights	1,365	(1,019)	346	1,382	(965)	417
Research and development technology rights	1,295	(1,028)	267	1,273	(947)	326
Total finite-lived intangible assets	31,979	(14,755)	17,224	31,991	(12,632)	19,359
Indefinite-lived intangible assets:						
In-process research and development	30	—	30	54	—	54
Total other intangible assets	\$ 32,009	\$ (14,755)	\$ 17,254	\$ 32,045	\$ (12,632)	\$ 19,413

Developed-product-technology rights consists of rights related to marketed products. Licensing rights primarily consists of contractual rights 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 primarily consists of rights related to the sale and distribution of marketed products. R&D technology rights pertains to technologies 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 September 30, 2020 and 2019, we recognized amortization associated with our finite-lived intangible assets of \$708 million and \$318 million, respectively. During the nine months ended September 30, 2020 and 2019, we recognized amortization associated with our finite-lived intangible assets of \$2.1 billion and \$948 million, respectively. Amortization of intangible assets is primarily included in Cost of sales in the Condensed Consolidated Statements of Income. The total estimated amortization for our finite-lived intangible assets for the remaining three months ending December 31, 2020, and the years ending December 31, 2021, 2022, 2023, 2024 and 2025, are \$0.7 billion, \$2.6 billion, \$2.5 billion, \$2.4 billion, \$2.4 billion and \$2.2 billion, respectively.

9. Financing arrangements

Our borrowings consisted of the following (in millions):

	September 30, 2020	December 31, 2019
4.50% notes due 2020 (4.50% 2020 Notes)	\$ —	\$ 300
2.125% notes due 2020 (2.125% 2020 Notes)	—	750
Floating Rate Notes due 2020	—	300
2.20% notes due 2020 (2.20% 2020 Notes)	—	700
3.45% notes due 2020 (3.45% 2020 Notes)	—	900
4.10% notes due 2021 (4.10% 2021 Notes)	—	1,000
1.85% notes due 2021 (1.85% 2021 Notes)	—	750
3.875% notes due 2021 (3.875% 2021 Notes)	1,450	1,750
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	1,465	1,402
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)	760	725
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
1.90% notes due 2025 (1.90% 2025 Notes)	500	—
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)	879	841
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)	614	630
2.20% notes due 2027 (2.20% 2027 Notes)	1,750	—
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)	904	928
2.45% notes due 2030 (2.45% 2030 Notes)	1,250	—
2.30% notes due 2031 (2.30% 2031 Notes)	1,250	—
6.375% notes due 2037 (6.375% 2037 Notes)	478	552
6.90% notes due 2038 (6.90% 2038 Notes)	254	291
6.40% notes due 2039 (6.40% 2039 Notes)	333	466
3.15% notes due 2040 (3.15% 2040 Notes)	2,000	—
5.75% notes due 2040 (5.75% 2040 Notes)	373	412
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	729	974
5.65% notes due 2042 (5.65% 2042 Notes)	415	487
5.375% notes due 2043 (5.375% 2043 Notes)	185	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
3.375% notes due 2050 (3.375% 2050 Notes)	2,250	—
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
2.77% notes due 2053 (2.77% 2053 Notes)	940	—
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(1,196)	(868)
Fair value adjustments	643	296
Other	5	—
Total carrying value of debt	34,287	29,903
Less current portion	(91)	(2,953)
Total long-term debt	\$ 34,196	\$ 26,950

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, the 4.663% 2051 Notes and the 2.77% 2053 Notes, which have effective interest rates of 6.3%, 5.6% and 5.2%, respectively.

Debt issuances and repayments

During the nine months ended September 30, 2020, we issued debt securities in the following offerings:

- In February 2020, we issued \$5.0 billion of debt consisting of \$500 million of the 1.90% 2025 Notes, \$750 million of the 2.20% 2027 Notes, \$1.25 billion of the 2.45% 2030 Notes, \$1.25 billion of the 3.15% 2040 Notes and \$1.25 billion of the 3.375% 2050 Notes.
- In May 2020, we issued \$4.0 billion of debt, including \$1.0 billion of the 2.20% 2027 Notes, \$750 million of the 3.15% 2040 Notes and \$1.0 billion of the 3.375% 2050 Notes, which represents a further issuance of, and which forms a single series with, each of the corresponding series of notes issued in February 2020, and \$1.25 billion of 2.30% 2031 Notes.

In the event of a change-in-control triggering event, as defined in the terms of the notes, we may be required to purchase all or a portion of these notes at a price equal to 101% of the principal amount of the notes plus accrued and unpaid interest. In addition, these notes may be redeemed at any time at our option, in whole or in part, at the principal amount of the notes being redeemed plus accrued and unpaid interest and a “make-whole” amount, which are defined by the terms of the notes. The notes may be redeemed without payment of make-whole amounts if redemption occurs during specified periods of time immediately prior to the maturity of the notes. Such time periods range from one month to six months prior to maturity.

A portion of the proceeds from the issuance of the notes in February 2020 was used to redeem the 3.45% 2020 Notes, the 4.10% 2021 Notes, the 1.85% 2021 Notes and the \$300 million aggregate principal amount of our 3.875% 2021 Notes. In connection with the redemption of these notes, we paid a total of \$50 million in make-whole amounts plus associated accrued and unpaid interest, all of which was recognized in Interest expense, net, in the Condensed Consolidated Statements of Income. In addition to these redemptions, the 4.50% 2020 Notes, the 2.125% 2020 Notes, the Floating Rate 2020 Notes and the 2.20% 2020 Notes matured and were repaid during the nine months ended September 30, 2020.

Interest rate swaps

In connection with the redemption of certain of the notes discussed above, associated interest rate swap contracts with an aggregate notional value of \$2.2 billion were terminated. In addition, because of historically low interest rates, during the three months ended March 31, 2020, we terminated interest rate swaps with an aggregate notional amount of \$5.2 billion that hedged the 3.625% 2024 Notes, the 2.60% 2026 Notes, the 4.663% 2051 Notes and portions of the 3.625% 2022 Notes and 3.125% 2025 Notes, which resulted in the receipt of \$576 million of cash and reduced counterparty credit risk. Immediately following the terminations of these contracts, we entered into new interest rate swap agreements at then-current interest rates on the same \$5.2 billion principal amount of notes. See Note 12, Derivative instruments.

The effective interest rates on notes for which we have entered into interest rate swap contracts and the related notional amounts of these contracts were as follows (dollar amounts in millions):

Notes	September 30, 2020		December 31, 2019	
	Notional amounts	Effective interest rates	Notional amounts	Effective interest rates
3.45% 2020 Notes	\$ —	LIBOR + 1.1%	\$ 900	LIBOR + 1.1%
4.10% 2021 Notes	—	LIBOR + 1.7%	1,000	LIBOR + 1.7%
3.875% 2021 Notes	1,450	LIBOR + 2.0%	1,750	LIBOR + 2.0%
3.625% 2022 Notes	750	LIBOR + 2.7%	750	LIBOR + 1.6%
3.625% 2024 Notes	1,400	LIBOR + 3.2%	1,400	LIBOR + 1.4%
3.125% 2025 Notes	1,000	LIBOR + 1.8%	1,000	LIBOR + 0.9%
2.60% 2026 Notes	1,250	LIBOR + 1.8%	1,250	LIBOR + 0.3%
4.663% 2051 Notes ⁽¹⁾	1,500	LIBOR + 2.6%	1,500	LIBOR + 0.0%
Total notional amounts	\$ 7,350		\$ 9,550	

⁽¹⁾ Excludes an additional 1.5% of interest for the difference between the coupon rate paid to noteholders and the fixed rate received under the interest rate swap contracts.

Debt exchange

During the three months ended September 30, 2020, we completed a private offering to exchange portions of certain outstanding senior notes due 2037 through 2043 (collectively, Old Notes), listed below, for the \$940 million principal amount of the newly issued 2.77% 2053 Notes (the Exchange Offer).

The following principal amounts of each series of Old Notes were validly tendered and subsequently cancelled in connection with the Exchange Offer (in millions):

	Principal amount exchanged
6.375% 2037 Notes	\$ 74
6.90% 2038 Notes	37
6.40% 2039 Notes	133
5.75% 2040 Notes	39
5.15% 2041 Notes	245
5.65% 2042 Notes	72
5.375% 2043 Notes	76

The 2.77% 2053 Notes bear interest at a lower fixed coupon rate while requiring higher principal repayment at a later maturity date as compared to those of the Old Notes that were exchanged. There were no other significant changes to the terms between the Old Notes and the 2.77% 2053 Notes. In connection with the Exchange Offer, \$85 million was paid to holders of the Old Notes (the cash consideration).

The Exchange Offer was accounted for as a debt modification, and accordingly, deferred financing costs and discounts associated with the Old Notes, the cash consideration and the \$264 million discount associated with the 2.77% 2053 Notes are being accreted over the term of these newly issued notes and recorded as Interest expense, net in the Condensed Consolidated Statements of Income.

10. Stockholders' equity

Stock repurchase program

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

	2020		2019	
	Shares	Dollars	Shares	Dollars
First quarter	4.3	\$ 933	15.9	\$ 3,031
Second quarter	2.6	591	13.1	2,349
Third quarter	3.0	752	6.2	1,170
Total stock repurchases	9.9	\$ 2,276	35.2	\$ 6,550

In December 2019, our Board of Directors increased the amount authorized under our stock repurchase program by an additional \$4.0 billion. As of September 30, 2020, \$4.2 billion of authorization remained available under our stock repurchase program.

Dividends

In July 2020, March 2020 and December 2019, the Board of Directors declared quarterly cash dividends of \$1.60 per share, which were paid in September 2020, June 2020 and March 2020, respectively. In October 2020, the Board of Directors declared a quarterly dividend of \$1.60 per share, which will be paid on December 8, 2020.

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, 2019	\$ (718)	\$ 175	\$ 22	\$ (7)	\$ (528)
Foreign currency translation adjustments	(52)	—	—	—	(52)
Unrealized (losses) gains	—	(162)	8	—	(154)
Reclassification adjustments to income	—	84	(33)	—	51
Other	—	—	—	(2)	(2)
Income taxes	—	17	6	—	23
Balance as of March 31, 2020	(770)	114	3	(9)	(662)
Foreign currency translation adjustments	(3)	—	—	—	(3)
Unrealized losses	—	(30)	(2)	—	(32)
Reclassification adjustments to income	—	(119)	—	—	(119)
Other	—	—	—	—	—
Income taxes	—	33	—	—	33
Balance as of June 30, 2020	(773)	(2)	1	(9)	(783)
Foreign currency translation adjustments	14	—	—	—	14
Unrealized gains	—	60	1	—	61
Reclassification adjustments to income	—	(224)	—	—	(224)
Other	—	—	—	(7)	(7)
Income taxes	—	36	—	—	36
Balance as of September 30, 2020	\$ (759)	\$ (130)	\$ 2	\$ (16)	\$ (903)

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

Components of AOCI	Three months ended September 30,		Condensed Consolidated Statements of Income locations
	2020	2019	
Cash flow hedges:			
Foreign currency contract gains	\$ 41	\$ 26	Product sales
Cross-currency swap contract gains (losses)	183	(64)	Interest and other income, net
	224	(38)	Income before income taxes
	(49)	8	Provision for income taxes
	<u>\$ 175</u>	<u>\$ (30)</u>	Net income
Available-for-sale securities:			
Net realized losses	\$ —	\$ (3)	Interest and other income, net
	—	—	Provision for income taxes
	<u>\$ —</u>	<u>\$ (3)</u>	Net income
Components of AOCI	Nine months ended September 30,		Condensed Consolidated Statements of Income locations
	2020	2019	
Cash flow hedges:			
Foreign currency contract gains	\$ 158	\$ 62	Product sales
Cross-currency swap contract gains (losses)	101	(92)	Interest and other income, net
	259	(30)	Income before income taxes
	(57)	6	Provision for income taxes
	<u>\$ 202</u>	<u>\$ (24)</u>	Net income
Available-for-sale securities:			
Net realized gains (losses)	\$ 33	\$ (9)	Interest and other income, net
	(7)	—	Provision for income taxes
	<u>\$ 26</u>	<u>\$ (9)</u>	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 September 30, 2020, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	\$ 174	\$ —	\$ —	\$ 174
U.S. Treasury bills	6,399	—	—	6,399
Corporate debt securities:				
Financial	—	—	—	—
Industrial	—	—	—	—
Other	—	—	—	—
Residential-mortgage-backed securities	—	—	—	—
Money market mutual funds	5,016	—	—	5,016
Other short-term interest-bearing securities	—	—	—	—
Equity securities	376	—	—	376
Derivatives:				
Foreign currency contracts	—	111	—	111
Cross-currency swap contracts	—	124	—	124
Interest rate swap contracts	—	109	—	109
Total assets	<u>\$ 11,965</u>	<u>\$ 344</u>	<u>\$ —</u>	<u>\$ 12,309</u>
Liabilities:				
Derivatives:				
Foreign currency contracts	\$ —	\$ 88	\$ —	\$ 88
Cross-currency swap contracts	—	481	—	481
Interest rate swap contracts	—	4	—	4
Contingent consideration obligations	—	—	54	54
Total liabilities	<u>\$ —</u>	<u>\$ 573</u>	<u>\$ 54</u>	<u>\$ 627</u>

Fair value measurement as of December 31, 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:				
Available-for-sale securities:				
U.S. Treasury notes	\$ 360	\$ —	\$ —	\$ 360
U.S. Treasury bills	—	—	—	—
Corporate debt securities:				
Financial	—	1,121	—	1,121
Industrial	—	834	—	834
Other	—	198	—	198
Residential-mortgage-backed securities	—	182	—	182
Money market mutual funds	5,250	—	—	5,250
Other short-term interest-bearing securities	—	289	—	289
Equity securities	303	—	—	303
Derivatives:				
Foreign currency contracts	—	224	—	224
Cross-currency swap contracts	—	66	—	66
Interest rate swap contracts	—	259	—	259
Total assets	<u>\$ 5,913</u>	<u>\$ 3,173</u>	<u>\$ —</u>	<u>\$ 9,086</u>
Liabilities:				
Derivatives:				
Foreign currency contracts	\$ —	\$ 31	\$ —	\$ 31
Cross-currency swap contracts	—	315	—	315
Interest rate swap contracts	—	—	—	—
Contingent consideration obligations	—	—	61	61
Total liabilities	<u>\$ —</u>	<u>\$ 346</u>	<u>\$ 61</u>	<u>\$ 407</u>

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.

Derivatives

All of our foreign currency forward derivative contracts have maturities of three years or less, and all are with counterparties that have minimum 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). 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 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.

During the three and nine months ended September 30, 2020 and 2019, 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 September 30, 2020 and December 31, 2019, the aggregate fair values of our borrowings were \$40.1 billion and \$33.7 billion, respectively, and the carrying values were \$34.3 billion and \$29.9 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 primarily associated 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 partially offset 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 contracts to hedge a portion of our projected international product sales—primarily over a three-year time horizon, with, at any given point in time, a higher percentage of nearer-term projected product sales being hedged than in successive periods.

As of September 30, 2020 and December 31, 2019, we had outstanding foreign currency forward contracts with aggregate notional amounts of \$4.8 billion and \$5.0 billion, respectively. We have designated these foreign currency forward contracts, which are primarily euro based, as cash flow hedges. Accordingly, we report the unrealized gains and losses on these contracts in AOCI in the Condensed Consolidated Balance Sheets, and we reclassify them to Product sales in the Condensed Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

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

The notional amounts and interest rates of our cross-currency swaps as of September 30, 2020, were as follows (notional amounts in millions):

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

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Condensed Consolidated Balance Sheets and are amortized into Interest expense, net, in the Condensed Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the nine months ended September 30, 2020, 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):

Derivatives in cash flow hedging relationships	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Foreign currency contracts	\$ (163)	\$ 176	\$ (25)	\$ 245
Cross-currency swap contracts	223	(105)	(107)	(240)
Total unrealized gains (losses)	\$ 60	\$ 71	\$ (132)	\$ 5

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified for and were designated as fair value hedges. These interest rate swap contracts effectively convert fixed-rate coupons to floating-rate LIBOR-based coupons over the terms of the related hedge contracts. As of September 30, 2020 and December 31, 2019, we had interest rate swap contracts with aggregate notional amounts of \$7.4 billion and \$9.6 billion, respectively, that hedge certain portions of our long-term debt issuances.

Interest rate swaps with an aggregate notional value of \$2.2 billion were terminated during the nine months ended September 30, 2020, in connection with the redemption of certain of our notes. The terminations of these interest rate swaps resulted in a gain of \$17 million, recognized in Interest expense, net, in the Condensed Consolidated Statements of Income. Additionally, we terminated \$5.2 billion aggregate notional amount of interest rate swaps, which resulted in the receipt of \$576 million from the counterparties that was included in Net cash provided by operating activities in the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2020. This amount will be recognized as a reduction in Interest expense, net, in the Condensed Consolidated Statements of Income over the remaining life of the underlying notes. Immediately following the terminations of these interest rate swap contracts, we entered into new interest rate swap agreements at then-current interest rates on the same \$5.2 billion principal amount of notes. See Note 9, Financing arrangements, for information on our interest rate swaps.

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):

Condensed Consolidated Balance Sheets locations	Carrying amounts of hedged liabilities ⁽¹⁾		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities ⁽²⁾	
	September 30, 2020	December 31, 2019	September 30, 2020	December 31, 2019
Current portion of long-term debt	\$ 89	\$ 903	\$ 89	\$ 4
Long-term debt	\$ 7,782	\$ 8,814	\$ 554	\$ 292

⁽¹⁾ Current portion of long-term debt includes \$89 million of carrying value with discontinued hedging relationships as of September 30, 2020. Long-term debt includes \$547 million and \$136 million of carrying value with discontinued hedging relationships as of September 30, 2020 and December 31, 2019, respectively.

⁽²⁾ Current portion of long-term debt includes \$89 million of hedging adjustments on discontinued hedging relationships as of September 30, 2020. Long-term debt includes \$447 million and \$36 million of hedging adjustments on discontinued hedging relationships as of September 30, 2020 and December 31, 2019, respectively.

Impact of hedging transactions

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

	Three months ended September 30, 2020			Nine months ended September 30, 2020		
	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	\$ 6,104	\$ 55	\$ (302)	\$ 17,906	\$ 69	\$ (944)
The effects of cash flow and fair value hedging:						
Gains on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency contracts	\$ 41	\$ —	\$ —	\$ 158	\$ —	\$ —
Cross-currency swap contracts	\$ —	\$ 183	\$ —	\$ —	\$ 101	\$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:						
Hedged items ⁽¹⁾	\$ —	\$ —	\$ 35	\$ —	\$ —	\$ 215
Derivatives designated as hedging instruments	\$ —	\$ —	\$ (13)	\$ —	\$ —	\$ (150)

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

⁽¹⁾ (Losses) gains on hedged items do not completely offset gains (losses) 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 and the recognition of gains on terminated hedges where the corresponding hedged item was paid down in the period.

No portions of our cash flow hedge contracts were excluded from the assessment of hedge effectiveness. As of September 30, 2020, we expected to reclassify \$34 million of net gains on our foreign currency and cross-currency swap contracts out of AOCI and into earnings during the next 12 months.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations in certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. Most of these exposures are hedged on a month-to-month basis. As of September 30, 2020 and December 31, 2019, the total notional amounts of these foreign currency forward contracts were \$1.0 billion and \$1.2 billion, respectively. Gains and losses recognized in earnings for our derivative instruments not designated as hedging instruments were not material for the three and nine months ended September 30, 2020 and 2019.

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

September 30, 2020	Derivative assets		Derivative liabilities	
	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	\$ 111	Accrued liabilities/ Other noncurrent liabilities	\$ 88
Cross-currency swap contracts	Other current assets/ Other assets	124	Accrued liabilities/ Other noncurrent liabilities	481
Interest rate swap contracts	Other current assets/ Other assets	109	Accrued liabilities/ Other noncurrent liabilities	4
Total derivatives designated as hedging instruments		344	573	
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	—	Accrued liabilities	—
Total derivatives not designated as hedging instruments		—	—	
Total derivatives		\$ 344	\$ 573	

December 31, 2019	Derivative assets		Derivative liabilities	
	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	\$ 223	Accrued liabilities/ Other noncurrent liabilities	\$ 31
Cross-currency swap contracts	Other current assets/ Other assets	66	Accrued liabilities/ Other noncurrent liabilities	315
Interest rate swap contracts	Other current assets/ Other assets	259	Accrued liabilities/ Other noncurrent liabilities	—
Total derivatives designated as hedging instruments		548	346	
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		\$ 549	\$ 346	

Our derivative contracts that were in liability positions as of September 30, 2020, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then-current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the contracts may be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

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

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, 2019, 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 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2019; and in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020.

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 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2019; or in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020, 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 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2019; or in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020, 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:

Abbreviated New Drug Application (ANDA) Patent Litigation

Otezla® ANDA Patent Litigation

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

On August 6, 2020, based on a joint request by Amgen and Mankind Pharma Ltd. (Mankind), the U.S. District Court for the District of New Jersey (the New Jersey District Court) entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Mankind's apremilast product during the term of U.S. Patent Nos. 6,962,940 (the '940 Patent); 7,659,302 (the '302 Patent); 8,455,536 (the '536 Patent); 9,018,243 (the '243 Patent); 9,724,330 (the '330 Patent); 7,427,638 (the '638 Patent); 7,893,101 (the '101 Patent); and 10,092,541 (the '541 Patent), unless authorized pursuant to a confidential settlement agreement. On August 14, 2020, based on a joint request by Amgen and Macleods Pharmaceuticals Ltd. (Macleods), the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Macleods's apremilast product during the term of the '638 Patent and the '541 Patent, unless authorized pursuant to a confidential settlement agreement. On October 7, 2020, based on a joint request by Amgen and Amneal Pharmaceuticals LLC (Amneal), the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Amneal's apremilast product during the term of the '101 Patent, the '940 Patent, the '638 Patent, the '302 Patent, the '536 Patent, the '243 Patent, the '330 Patent and the '541 Patent, unless authorized pursuant to a confidential settlement agreement.

Trial in the consolidated action against the remaining defendants is scheduled to commence on June 14, 2021.

Sensipar® (cinacalcet) ANDA Patent Litigation

On September 8, 2020, the U.S. District Court for the District of Delaware (the Delaware District Court) entered judgment of validity and infringement of our U.S. Patent No. 9,375,405 (the '405 Patent) in the lawsuit filed against Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal) and, except to the extent specifically authorized in a confidential settlement agreement, enjoined Amneal from infringing the '405 Patent by making, using, selling, offering to sell or importing Amneal's cinacalcet product during the term of the patent.

A hearing before the Delaware District Court on the request of Piramal Healthcare UK Limited (Piramal) to recover damages for being enjoined during the pendency of Amgen's appeal has been rescheduled for February 21, 2021. On October 14, 2020, the Delaware District Court issued an order permitting Slate Run Pharmaceuticals, LLC, Piramal's business partner, to intervene in the pending action.

ENBREL Patent Litigation

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

On September 29, 2020, the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court) denied the petition for rehearing of Sandoz Inc., Sandoz International GmbH and Sandoz GmbH filed on July 31, 2020.

Repatha Patent Litigation

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

On October 21, 2020, the Federal Circuit Court set the hearing on Amgen's appeal for December 9, 2020.

NEUPOGEN® (filgrastim)/Neulasta® Patent Litigation

Apotex Patent Trial and Appeal Board (PTAB) Challenge

On July 14, 2020, Amgen and Apotex Inc. and Apotex Corp. (Apotex) filed a joint motion to terminate the inter partes review proceedings stating that there is no current dispute between the parties with respect to U.S. Patent No. 8,952,138 (the '138 Patent). On July 29, 2020, the United States government filed a petition for writ of certiorari with respect to the cases that the Federal Circuit Court remanded to the PTAB of the U.S. Patent and Trademark Office, including the case regarding the '138 Patent, for proceedings consistent with its decision in *Arthrex Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), requesting that such remanded cases be held pending the U.S. Supreme Court's disposition of the petition for writ of certiorari in *United States v. Arthrex, Inc.*, No. 19-1434. On August 25, 2020, Amgen filed its response to the United States government's petition for writ of certiorari indicating that Amgen did not intend to respond unless requested by the U.S. Supreme Court.

Amgen Inc., et al. v. Pfizer Inc. et al.

On July 10, 2020, Pfizer Inc. and Hospira Inc. (collectively, Pfizer) requested that the Delaware District Court stay the patent infringement lawsuit Amgen filed against Pfizer on U.S. Patent No. 10,577,392 (the '392 Patent) until the co-pending patent infringement lawsuit on U.S. Patent No. 9,643,997 is resolved. Amgen has opposed Pfizer's motion for a stay and seeks to avoid delay in the Delaware District Court's resolution of the '392 Patent dispute.

Breach of Contract Action

Novartis Pharma AG v. Amgen Inc.

On September 14, 2020, Amgen's motion for clarification and/or reconsideration of the U.S. District Court for the Southern District of New York's June 9, 2020 order was denied.

Antitrust Class Action

Sensipar[®] Antitrust Class Actions

On August 5, 2020, the plaintiffs filed objections to the U.S. Magistrate Judge for the District of Delaware's report and recommendation issued on July 22, 2020. On August 19, 2020, Amgen filed a response to the plaintiffs' objections.

Humira[®] Biosimilar Antitrust Class Actions

On July 28, 2020, the plaintiffs in the antitrust class action lawsuit filed a notice of appeal. On October 5, 2020, the plaintiffs filed their opening brief to the U.S. Court of Appeals for the Seventh Circuit. Amicus briefs were filed on behalf of the plaintiffs, including one by the Federal Trade Commission and one on behalf of 20 states, both filed on October 13, 2020.

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, 2019, and our Quarterly Report on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020. 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 and in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2019, and in Part II, Item 1A. Risk Factors of our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020. 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, collaborations and effects of pandemics. 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 biotechnology company committed to unlocking the potential of biology for patients suffering from serious illnesses. 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. In 2020, we are celebrating our 40th anniversary, continuing our history of focusing on innovative medicines that have the potential to be first-in-class molecules and that have a large-effect size on serious diseases.

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

COVID-19 pandemic

A novel strain of coronavirus (SARS-CoV-2, or severe acute respiratory syndrome coronavirus 2, causing coronavirus disease 19, or COVID-19) was declared a global pandemic by the World Health Organization (WHO) on March 11, 2020. We have been carefully monitoring the COVID-19 pandemic and its impact on our global operations. We have taken appropriate steps to minimize the risk to our employees. A significant number of our employees have been working remotely, with the exception of certain staff that require access to our manufacturing and laboratory research facilities, in accordance with applicable government health and safety protocols and guidance issued in response to the COVID-19 pandemic. To date, our remote working arrangements have not significantly affected our ability to maintain critical business operations, and we have not experienced disruptions or shortages of our supply of medicines.

Since the beginning of the COVID-19 pandemic, we have seen changes in demand trends for some of our products, including lower demand for certain products as continuing patient access to those products has been affected by COVID-19, particularly in the early phases of the pandemic. For example, near the end of March, we began to observe a decline in sales of Prolia[®], as elderly patients, who are relatively more vulnerable to COVID-19, avoided doctors' offices. Demand has since recovered to varying degrees by product as local conditions improved in certain geographies that opened after an initial improvement in COVID-19 infection rates, allowing patients to resume receiving their treatments. During the third quarter, our own efforts remain focused on assisting patients with improving their continuity of care to increase product access as compared to what they experienced during the earlier stages of the pandemic. Recently, higher infections have been observed in certain geographies, including the United States and Europe, which may further restrict demand similar to early phases of the pandemic. As a result, we expect to see continued volatility through at least the duration of the pandemic as governments respond to current local conditions.

The majority of clinical trials that were paused at the onset of the pandemic to ensure subject safety or data integrity have resumed. While some study enrollments are increasing, overall study recruitment continues to be impacted by the pandemic. We continuously monitor and reevaluate the status of studies, pausing when uncertainty arises with regard to the trial sites' ability to ensure safety or data integrity. We remain focused on supporting our active clinical sites in providing care for these patients and in providing investigational drug supply. In addition, our R&D organization is supporting efforts to combat the COVID-19 pandemic in a number of ways, including by (i) conducting research in support of therapeutic antibodies that could diminish the impact of COVID-19 on patients, (ii) joining a public-private partnership between leading companies in our industry and U.S. government health agencies to develop a strategy for a coordinated research response and (iii) investigating Otezla[®] as a potential immunomodulatory treatment in adult patients hospitalized with severe COVID-19 infections through platform trials.

We continue to 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 expenditures and debt service requirements as well as to engage in the capital-return and other business initiatives that we plan to strategically pursue. In addition, in the second quarter of this year, we issued \$4.0 billion of long-term debt for general corporate purposes, including enhancing our working capital position. For a discussion of the risks presented by the COVID-19 pandemic to our results, see Risk Factors in Part II, Item 1A. of this Form 10-Q.

Significant developments

Following is a summary of selected significant developments affecting our business that have occurred since the filing of our Quarterly Report on Form 10-Q for the period ended June 30, 2020. 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, 2019, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020.

Oncology/Hematology

KYPROLIS[®]

- In August 2020, we announced that the U.S. Food and Drug Administration (FDA) had approved the expansion of the KYPROLIS[®] U.S. prescribing information to include its use in combination with DARZALEX[®] (daratumumab) plus dexamethasone (DKd) in two dosing regimens — once weekly and twice weekly — for the treatment of patients with relapsed or refractory multiple myeloma (R/R MM) who have received one to three previous lines of therapy.

Sotorasib

- In September 2020, we announced updated phase 1 data evaluating sotorasib in 129 patients across multiple advanced solid tumors with KRAS G12C mutation, which were published in the New England Journal of Medicine. Data from 59 patients with advanced non-small cell lung cancer (NSCLC) were also featured in an oral presentation at a September 2020 medical conference. In the patients with advanced NSCLC who were treated with the 960 mg daily dose, the confirmed objective response rate (ORR) was 35.3%. Across all dose levels, the confirmed ORR was 32.2% with median duration of response of 10.9 months and median progression-free survival of 6.3 months; 10 of 19 responders were still in response as of the data cutoff.
- In October 2020, we announced topline phase 2 results in 126 patients with KRAS G12C-mutant advanced NSCLC. Sotorasib demonstrated an objective response rate (primary endpoint) consistent with previously reported phase 1 data in patients taking the 960 mg daily dose. Other measures of efficacy, including duration of response, were promising, and more than half of the responders were still on treatment and continuing to respond as of the data cutoff date. The results of this phase 2 study are potentially registrational, and a phase 3 confirmatory study comparing sotorasib to docetaxel is currently recruiting patients with KRAS G12C-mutant advanced NSCLC.

Cardiovascular

Omecamtiv mecarbil

- In October 2020, along with collaborator Cytokinetics and funding and strategic partner Servier, we announced topline results from the phase 3 trial of omecamtiv mecarbil in patients with heart failure with reduced ejection fraction (HFrEF). The trial met its primary composite efficacy endpoint and demonstrated a statistically significant effect to reduce cardiovascular (CV) death or heart failure events compared to placebo in patients with standard of care (hazard ratio: 0.92; 95% confidence interval: 0.86, 0.99, p-value=0.0252). No reduction in the secondary endpoint of CV death was observed.

Selected financial information

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
Product sales						
U.S.	\$ 4,618	\$ 4,029	15 %	\$ 13,325	\$ 12,162	10 %
ROW	1,486	1,434	4 %	4,581	4,161	10 %
Total product sales	6,104	5,463	12 %	17,906	16,323	10 %
Other revenues	319	274	16 %	884	842	5 %
Total revenues	\$ 6,423	\$ 5,737	12 %	\$ 18,790	\$ 17,165	9 %
Operating expenses	\$ 3,970	\$ 3,261	22 %	\$ 11,659	\$ 9,539	22 %
Operating income	\$ 2,453	\$ 2,476	(1)%	\$ 7,131	\$ 7,626	(6)%
Net income	\$ 2,021	\$ 1,968	3 %	\$ 5,649	\$ 6,139	(8)%
Diluted EPS	\$ 3.43	\$ 3.27	5 %	\$ 9.54	\$ 10.01	(5)%
Diluted shares	589	602	(2)%	592	613	(3)%

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 increased for the three and nine months ended September 30, 2020, primarily driven by unit demand increases from newer brands including Otezla[®], acquired in November 2019, MVASI[®], KANJINTI[®] and Repatha[®]. These unit demand increases were partially offset by declines in net selling prices for certain products, unit demand declines for mature brands that face biosimilar or generic competition and the effects of the COVID-19 pandemic. For the remainder of 2020, we expect that continued competition against our mature brands will result in both unit demand and net selling price declines. Looking forward, we also expect increasing competition against our biosimilar products.

During the initial stages of the COVID-19 pandemic, we experienced changes in demand trends for some of our products. The pandemic interrupted many physician–patient interactions, which led to delays in diagnosis and treatment, with varying degrees of impact across our portfolio. In general, sales of negatively affected products fell the most in the early part of the second quarter, with product demand beginning to recover in the later weeks of the second quarter and continuing through the third quarter. However, given the unpredictable nature of the pandemic, it is possible that there could be intermittent disruptions in physician–patient interactions going forward and thus we continue to expect quarter-to-quarter variability. See Risk Factors in Part II, Item 1A. of this Form 10-Q.

In addition, other changes in the healthcare ecosystem introduce variability into product sales trends. For example, changes in U.S. employment could lead to changes to the insured population, with growth in Medicaid enrollees and uninsured individuals having a negative impact on revenues. Overall, there is increased uncertainty around the timing and magnitude of our sales during the COVID-19 pandemic.

Other revenues increased for the three and nine months ended September 30, 2020, primarily driven by higher royalties.

Operating expenses increased for the three and nine months ended September 30, 2020, primarily driven by acquisition- and commercial-related expenses for Otezla[®]. For the remainder of 2020, we expect operating expenses to continue to see the effects of our acquisition of Otezla[®] and to exhibit our historical expense patterns.

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 partially offset by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material for the three and nine months ended September 30, 2020 and 2019.

Results of operations

Product sales

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
ENBREL	\$ 1,325	\$ 1,366	(3)%	\$ 3,724	\$ 3,880	(4)%
Prolia [®]	701	630	11 %	2,014	1,920	5 %
Neulasta [®]	555	711	(22)%	1,757	2,556	(31)%
Otezla [®]	538	—	N/A	1,578	—	N/A
XGEVA [®]	481	476	1 %	1,397	1,446	(3)%
Aranesp [®]	384	452	(15)%	1,193	1,302	(8)%
KYPROLIS [®]	260	266	(2)%	793	778	2 %
Repatha [®]	205	168	22 %	634	461	38 %
Other products	1,655	1,394	19 %	4,816	3,980	21 %
Total product sales	\$ 6,104	\$ 5,463	12 %	\$ 17,906	\$ 16,323	10 %

Future sales of our products will depend in part on the factors discussed below and in the following sections of this report: (i) Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview and Selected Financial Information; and (ii) Part II, Item 1A. Risk Factors; and in the following sections of our Annual Report on Form 10-K for the year ended December 31, 2019: (i) Item 1. Business—Marketing, Distribution and Selected Marketed Products, (ii) Item 1A. Risk Factors and (iii) Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview, and Results of Operations—Product Sales, as well as in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020, in (i) Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Product Sales; and (ii) Part II, Item 1A. Risk Factors.

ENBREL

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
ENBREL — U.S.	\$ 1,289	\$ 1,323	(3)%	\$ 3,619	\$ 3,744	(3)%
ENBREL — Canada	36	43	(16)%	105	136	(23)%
Total ENBREL	\$ 1,325	\$ 1,366	(3)%	\$ 3,724	\$ 3,880	(4)%

The decrease in ENBREL sales for the three and nine months ended September 30, 2020, was primarily driven by lower unit demand, partially offset by favorable changes to estimated sales deductions. Consistent with prior periods, ENBREL has continued to lose market share, and this decline has been compounded by a reduction in the growth rate of the rheumatology market as a result of COVID-19.

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 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2019, 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, 2020, June 30, 2020 and September 30, 2020. Other companies are also developing proposed biosimilar versions of ENBREL.

Companies with approved biosimilar versions of ENBREL may seek to enter the U.S. market if we are not ultimately successful in our litigations, or even earlier.

Prolia[®]

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
Prolia [®] — U.S.	\$ 478	\$ 425	12 %	\$ 1,341	\$ 1,273	5 %
Prolia [®] — ROW	223	205	9 %	673	647	4 %
Total Prolia [®]	\$ 701	\$ 630	11 %	\$ 2,014	\$ 1,920	5 %

Prior to the COVID-19 pandemic, Prolia[®] had exhibited a historical sales pattern, with the first and third quarters of each year representing lower sales than the second and fourth quarters of a year. This is primarily due to the six-month dosing interval of Prolia[®]. However, disruptions in patient visits as a result of the pandemic affected demand during the first half of 2020 and altered historical trends. Many patients who delayed treatment earlier in the year have since resumed treatment resulting in higher unit demand that contributed to an overall increase in global Prolia[®] sales for the three months ended September 30, 2020. The increase in global Prolia[®] sales for the nine months ended September 30, 2020, was driven by higher unit demand, and to a lesser extent, net selling price. Given the impact of the pandemic in the second quarter and the six-month dosing regimen of Prolia[®], we expect year-over-year growth rates in the fourth quarter to be lower than pre-COVID-19 growth trends.

Neulasta[®]

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
Neulasta [®] — U.S.	\$ 484	\$ 619	(22)%	\$ 1,538	\$ 2,231	(31)%
Neulasta [®] — ROW	71	92	(23)%	219	325	(33)%
Total Neulasta [®]	\$ 555	\$ 711	(22)%	\$ 1,757	\$ 2,556	(31)%

The decrease in global Neulasta[®] sales for the three and nine months ended September 30, 2020, was driven by the impact of biosimilar competition on unit demand and net selling price. For the three months ended September 30, 2020, the aforementioned decrease was partially offset by favorable changes to estimated sales deductions. Neulasta[®] sales included a \$98 million order from the U.S. government in the first quarter of 2019.

We face increased competition in the United States and Europe as a result of launches of biosimilar versions of Neulasta[®], which has had and will continue to have a material adverse impact on sales. We also expect another biosimilar version to be approved in the future. For a discussion of ongoing patent litigations related to these and other biosimilars, see Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2019, 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, 2020, June 30, 2020 and September 30, 2020.

Otezla®

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
Otezla® — U.S.	\$ 439	\$ —	N/A	\$ 1,280	\$ —	N/A
Otezla® — ROW	99	—	N/A	298	—	N/A
Total Otezla®	\$ 538	\$ —	N/A	\$ 1,578	\$ —	N/A

Otezla® was acquired on November 21, 2019, and generated \$538 million and \$1.6 billion in sales for the three and nine months ended September 30, 2020, respectively.

XGEVA®

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
XGEVA® — U.S.	\$ 363	\$ 356	2 %	\$ 1,036	\$ 1,091	(5)%
XGEVA® — ROW	118	120	(2)%	361	355	2 %
Total XGEVA®	\$ 481	\$ 476	1 %	\$ 1,397	\$ 1,446	(3)%

The increase in global XGEVA® sales for the three months ended September 30, 2020, was primarily driven by a slight buildup of inventory at U.S. wholesalers, partially offset by unfavorable changes to estimated sales deductions. The decrease in global XGEVA® sales for the nine months ended September 30, 2020, was primarily driven by lower unit demand as a result of the COVID-19 pandemic.

Aranesp®

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
Aranesp® — U.S.	\$ 158	\$ 204	(23)%	\$ 489	\$ 578	(15)%
Aranesp® — ROW	226	248	(9)%	704	724	(3)%
Total Aranesp®	\$ 384	\$ 452	(15)%	\$ 1,193	\$ 1,302	(8)%

The decrease in global Aranesp® sales for the three and nine months ended September 30, 2020, was driven by declines in net selling price and unit demand.

Aranesp® faces competition from a long-acting erythropoiesis-stimulating agent (ESA). Aranesp® also faces competition from a biosimilar version of EPOGEN®. For the remainder of 2020, we expect that sales will continue to decline at a faster rate than in 2019 due to short- and long-acting competition.

KYPROLIS®

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
KYPROLIS® — U.S.	\$ 173	\$ 163	6 %	\$ 527	\$ 483	9 %
KYPROLIS® — ROW	87	103	(16)%	266	295	(10)%
Total KYPROLIS®	\$ 260	\$ 266	(2)%	\$ 793	\$ 778	2 %

The decrease in global KYPROLIS[®] sales for the three months ended September 30, 2020, was driven by lower unit demand as a result of the COVID-19 pandemic. The increase in global KYPROLIS[®] sales for the nine months ended September 30, 2020, was driven by an increase in net selling price, partially offset by lower unit demand.

We are engaged in litigation with two related companies that are challenging our material patents related to KYPROLIS[®] and that are seeking to market generic carfilzomib products. 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 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2019, 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, 2020 and June 30, 2020. The FDA has reported that it has finally approved ANDAs filed by two companies for generic carfilzomib products and tentatively approved ANDAs filed by two other companies. The date of final approval of ANDAs for generic carfilzomib products is governed by the Hatch-Waxman Act and any applicable settlement agreements between the parties.

Repatha[®]

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
Repatha [®] — U.S.	\$ 92	\$ 85	8 %	\$ 331	\$ 259	28 %
Repatha [®] — ROW	113	83	36 %	303	202	50 %
Total Repatha [®]	<u>\$ 205</u>	<u>\$ 168</u>	<u>22 %</u>	<u>\$ 634</u>	<u>\$ 461</u>	<u>38 %</u>

The increase in global Repatha[®] sales for the three months ended September 30, 2020, was primarily driven by higher unit demand, partially offset by lower net selling price and unfavorable changes to estimated sales deductions. The increase in global Repatha[®] sales for the nine months ended September 30, 2020, was primarily driven by higher unit demand, partially offset by lower net selling price.

Other products

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
Nplate [®] — U.S.	\$ 118	\$ 119	(1)%	\$ 352	\$ 355	(1)%
Nplate [®] — ROW	94	76	24 %	271	230	18 %
Vectibix [®] — U.S.	90	79	14 %	249	236	6 %
Vectibix [®] — ROW	103	117	(12)%	341	326	5 %
Parsabiv [®] — U.S.	156	137	14 %	462	394	17 %
Parsabiv [®] — ROW	27	20	35 %	82	57	44 %
MVASI [®] — U.S.	185	42	*	442	42	*
MVASI [®] — ROW	46	1	*	76	1	*
EPOGEN [®] — U.S.	149	215	(31)%	465	657	(29)%
KANJINTI [®] — U.S.	149	39	*	346	39	*
KANJINTI [®] — ROW	18	30	(40)%	63	84	(25)%
BLINCYTO [®] — U.S.	54	47	15 %	167	126	33 %
BLINCYTO [®] — ROW	35	38	(8)%	109	106	3 %
Aimovig [®] — U.S.	105	66	59 %	274	208	32 %
EVENITY [®] — U.S.	54	12	*	131	15	*
EVENITY [®] — ROW	5	47	(89)%	129	89	45 %
Sensipar [®] — U.S.	7	38	(82)%	81	216	(63)%
Sensipar [®] /Mimpara [®] — ROW	32	71	(55)%	162	228	(29)%
AMGEVITA [™] — ROW	80	61	31 %	228	144	58 %
NEUPOGEN [®] — U.S.	44	32	38 %	117	137	(15)%
NEUPOGEN [®] — ROW	21	22	(5)%	62	65	(5)%
Other — U.S.	31	28	11 %	78	78	— %
Other — ROW	52	57	(9)%	129	147	(12)%
Total other products	\$ 1,655	\$ 1,394	19 %	\$ 4,816	\$ 3,980	21 %
Total U.S. — other products	\$ 1,142	\$ 854	34 %	\$ 3,164	\$ 2,503	26 %
Total ROW — other products	513	540	(5)%	1,652	1,477	12 %
Total other products	\$ 1,655	\$ 1,394	19 %	\$ 4,816	\$ 3,980	21 %

* Change in excess of 100%.

Operating expenses

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

	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	Change	2020	2019	Change
Operating expenses:						
Cost of sales	\$ 1,561	\$ 1,036	51 %	\$ 4,562	\$ 3,103	47 %
% of product sales	25.6 %	19.0 %		25.5 %	19.0 %	
% of total revenues	24.3 %	18.1 %		24.3 %	18.1 %	
Research and development	\$ 1,062	\$ 1,001	6 %	\$ 2,978	\$ 2,804	6 %
% of product sales	17.4 %	18.3 %		16.6 %	17.2 %	
% of total revenues	16.5 %	17.4 %		15.8 %	16.3 %	
Selling, general and administrative	\$ 1,346	\$ 1,223	10 %	\$ 3,957	\$ 3,637	9 %
% of product sales	22.1 %	22.4 %		22.1 %	22.3 %	
% of total revenues	21.0 %	21.3 %		21.1 %	21.2 %	
Other	\$ 1	\$ 1	— %	\$ 162	\$ (5)	*

* Change in excess of 100%.

Cost of sales

Cost of sales increased to 24.3% of total revenues for the three and nine months ended September 30, 2020, driven by the amortization of expenses related to our acquisition of Otezla[®]. For the nine months ended September 30, 2020, the aforementioned increase was partially offset by lower manufacturing costs.

Research and development

The increases in R&D expense for the three and nine months ended September 30, 2020, were driven by higher late-stage program support, including sotorasib, biosimilar programs and Otezla[®], partially offset by recoveries from our collaboration with BeiGene that reduced expenses in late-stage program support and in research and early pipeline.

Selling, general and administrative

The increase in Selling, general and administrative (SG&A) expense for the three months ended September 30, 2020, was driven by Otezla[®] commercial-related expenses. The increase in SG&A expense for the nine months ended September 30, 2020, was driven by Otezla[®] commercial- and acquisition-related expenses, partially offset by lower spend from recently launched and growth products.

Other

Other operating expenses for the nine months ended September 30, 2020, primarily consisted of legal settlement expenses. Other operating expenses for the nine months ended September 30, 2019, included changes in the fair values of contingent consideration liabilities related to business combinations.

See the Overview and Selected financial information sections above for discussion of impacts to operating expenses from the COVID-19 pandemic.

Nonoperating expense/income and income taxes

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Interest expense, net	\$ 302	\$ 313	\$ 944	\$ 988
Interest and other income, net	\$ 55	\$ 114	\$ 69	\$ 517
Provision for income taxes	\$ 185	\$ 309	\$ 607	\$ 1,016
Effective tax rate	8.4 %	13.6 %	9.7 %	14.2 %

Interest expense, net

The decrease in Interest expense, net, for the three months ended September 30, 2020, was primarily due to lower LIBOR rates on debt for which we effectively pay a variable rate of interest, partially offset by a higher average debt balance.

The decrease in Interest expense, net, for the nine months ended September 30, 2020, was primarily due to lower LIBOR rates on debt for which we effectively pay a variable rate of interest, partially offset by net costs associated with the early retirement of debt.

Interest and other income, net

The decrease in Interest and other income, net, for the three and nine months ended September 30, 2020, was primarily due to reduced interest income as a result of lower average cash balances and a decline in interest yields.

Income taxes

The decrease in our effective tax rate for the three and nine months ended September 30, 2020, was primarily due to favorable items in the quarter, including effective settlement of certain federal income tax matters and adjustments to prior year tax liabilities, partially offset by changes in jurisdictional mix of earnings. The tax rate for the nine months ended September 30, 2020 was also favorably affected by amortization related to the Otezla[®] acquisition.

On March 27, 2020, in response to the COVID-19 pandemic, the president of the United States signed the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which provides additional economic stimulus to address the impact of the COVID-19 pandemic. We do not expect there to be any significant benefit to our income tax provision as a result of the CARES Act, and we continue to monitor for any potential tax legislation related to the COVID-19 pandemic.

In April 2017, we received an RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposed to make significant adjustments that primarily relate 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 calculations but continues to propose substantial adjustments. We disagree with the proposed adjustments and calculations and the matter is currently within the jurisdiction of the IRS administrative appeals office. If we are unable to reach resolution, we will vigorously contest the proposed adjustments through the judicial process. In addition, in May 2020, we received an RAR from the IRS for the years 2013, 2014 and 2015 proposing adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. In September 2020, we received a revised RAR that continues to propose substantial adjustments for the years 2013, 2014 and 2015. We disagree with the proposed adjustments and calculations, and will pursue resolution with the IRS administrative appeals office. Final resolution of these complex matters 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 substantially 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):

	September 30, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	\$ 12,360	\$ 8,911
Total assets	\$ 64,637	\$ 59,707
Current portion of long-term debt	\$ 91	\$ 2,953
Long-term debt	\$ 34,196	\$ 26,950
Stockholders' equity	\$ 10,959	\$ 9,673

Cash, cash equivalents and marketable securities

We have global access to our \$12.4 billion balance of cash, cash equivalents and marketable securities. The primary objective of our investment portfolio is to maintain 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 primarily issued by institutions with 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 deploy our accumulated cash balances in a strategic manner and consider a number of alternatives, including strategic transactions (including those that expand our portfolio of products in areas of therapeutic interest), repayment of debt, payment of dividends and stock repurchases.

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 our overall level of cash, stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include private block purchases, tender offers and market transactions.

In July 2020, March 2020 and December 2019, the Board of Directors declared quarterly cash dividends of \$1.60 per share of common stock, which were paid on September 8, 2020, June 8, 2020 and March 6, 2020, respectively, an increase of 10% over the quarterly cash dividend paid in each quarter of 2019. In October 2020, the Board of Directors declared a quarterly dividend of \$1.60 per share, which will be paid on December 8, 2020.

We have also returned capital to stockholders through our stock repurchase program. During the nine months ended September 30, 2020, we executed trades to repurchase \$2.3 billion of common stock. As of September 30, 2020, \$4.2 billion of authorization remained available under our stock repurchase program.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of September 30, 2020 and December 31, 2019. 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. For example, we issued \$5.0 billion of long-term debt during the three months ended March 31, 2020, to payoff long-term debt maturing in the near term, and \$4.0 billion of long-term debt during three months ended June 30, 2020, for general corporate purposes, including enhancing our working capital position. See our Annual Report on Form 10-K for the year ended December 31, 2019, Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business.*

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which requires that we maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of September 30, 2020.

Cash flows

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

	Nine months ended September 30,	
	2020	2019
Net cash provided by operating activities	\$ 8,344	\$ 6,636
Net cash (used in) provided by investing activities	\$ (4,017)	\$ 11,672
Net cash used in financing activities	\$ (1,277)	\$ (13,838)

Operating

Cash provided by operating activities is expected to be our primary recurring source of funds. Cash provided by operating activities during the nine months ended September 30, 2020, increased compared with the same period in the prior year primarily due to higher Net income, after adjustments for noncash items, the current year monetization of interest rate swap contracts and timing of payments to corporate partners.

Investing

Cash used in investing activities during the nine months ended September 30, 2020, was primarily due to our \$3.2 billion of equity investments, primarily BeiGene, and net cash outflows related to marketable securities of \$394 million. Cash provided by investing activities during the nine months ended September 30, 2019, was primarily due to net cash inflows related to marketable securities of \$12.4 billion. Capital expenditures for the nine months ended September 30, 2020 and 2019, were \$435 million and \$430 million, respectively. We currently estimate 2020 spending on capital projects to be approximately \$600 million.

Financing

Cash used in financing activities during the nine months ended September 30, 2020, was primarily due to repayment of debt of \$5.0 billion, the payment of dividends of \$2.8 billion and payments to repurchase our common stock of \$2.3 billion, substantially offset by proceeds from the issuance of debt of \$8.9 billion. Cash used in financing activities during the nine months ended September 30, 2019, was primarily due to payments to repurchase our common stock of \$6.6 billion, repayment of debt of \$4.5 billion and payment of dividends of \$2.6 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, 2019.

During the nine months ended September 30, 2020, our critical accounting policies were changed to include our assessment of impairment of equity method investments. We review the carrying value of our equity method investments whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. We record impairment losses on our equity method investments if we deem the impairment to be other-than-temporary. We deem an impairment to be other-than-temporary based on various factors, including but not limited to, the length of time and the extent to which the fair value is below the carrying value, volatility of the security price, the financial condition of the issuer, changes in technology that may impair the earnings potential of the investment and our intent and ability to retain the investment to allow for a recovery in fair value. We believe our judgments used in assessing impairment of equity method investments are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

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, 2019, and is incorporated herein by reference. Except as noted below, there have been no material changes during the nine months ended September 30, 2020, 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, 2019.

In February and May 2020, we issued an aggregate face amount of \$9.0 billion in long-term debt with a weighted-average maturity of approximately 16 years and redeemed/repaid approximately \$5.0 billion of debt, all with maturities of less than two years. These changes increased the sensitivity of fluctuations in fair value of our outstanding long-term debt resulting from changes in market interest rates. A hypothetical 100 basis point decrease in interest rates relative to interest rates at September 30, 2020 and December 31, 2019, would have resulted in increases of \$4.5 billion and \$3.0 billion, respectively, in the aggregate fair values of our outstanding long-term debt on each of these dates. These amounts do not consider the impact that hypothetical changes in interest rates would have on our associated interest rate swap and cross-currency swap contracts.

During the nine months ended September 30, 2020, we terminated interest rate swaps with an aggregate notional amount of \$5.2 billion with respect to certain of our long-term debt, which resulted in the receipt of \$576 million of cash and reduced counterparty credit risk. Immediately following termination of these contracts, we entered into new interest rate swap agreements at then-current interest rates on the same \$5.2 billion principal amount of notes. See Note 9, Financing arrangements, and Note 12, Derivative instruments, to the condensed consolidated financial statements for further discussion.

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 facilitate timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen’s management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and, in reaching a reasonable level of assurance, Amgen’s management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen’s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen’s disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2020.

Management determined that, as of September 30, 2020, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

See Note 13, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020, June 30, 2020 and September 30, 2020, for discussions that are limited to certain recent developments concerning our legal proceedings. Those discussions should be read in conjunction with Note 19, 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, 2019.

Item 1A. RISK FACTORS

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

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, 2019, provide additional disclosure for these supplemental risks and are incorporated herein by reference.

The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations.

The novel coronavirus identified in late 2019, SARS-CoV-2, which causes the disease known as COVID-19, is an ongoing global pandemic that has resulted in public and governmental efforts to contain or slow the spread of the disease, including widespread shelter-in-place orders, social distancing interventions, quarantines, travel restrictions and various forms of operational shutdowns. The COVID-19 pandemic and the resulting measures implemented in response to the pandemic are adversely affecting, and is expected to continue to adversely affect, a number of our business activities (including our research and development, clinical trials, operations, supply chains, distribution systems, product development and sales activities) as well as those of our suppliers, customers, third-party payers and patients. Due to the pandemic and these measures and their effects, we have experienced, and expect to continue to experience, unpredictable reductions in demand for certain of our products, and in some cases, have experienced, and could continue to experience, unpredictable increases in demand for certain of our products.

Our clinical trials have been, and are expected to continue to be, adversely affected by the COVID-19 pandemic. We have clinical work ongoing at investigational sites across the globe. A number of clinical trial sites, including those in regions experiencing new or resurgent outbreaks of COVID-19, have restricted site visits and have imposed restrictions on the initiation of new clinical trials and patient visits, to protect both site staff and patients from possible COVID-19 exposure that has stopped or slowed clinical trial activities. In response to the safety concerns related to COVID-19, we have suspended, and will continue to suspend, enrollment and screening in clinical trials where sites are unable to perform clinical trial work due to COVID-19 or there is uncertainty around the ability of sites to ensure subject safety or data integrity. Further, the COVID-19 pandemic is expected to adversely affect our ability to continue enrollment of certain required post-marketing studies, including pediatric studies. While many of our clinical trial activities have recommenced in recent months, the initial disruption caused by the COVID-19 pandemic to our clinical trials and our clinical trial plans and timelines, and any similar future disruptions, may have a significant adverse effect on our product development and launches, and, in turn, on future product sales, business and results of operations. For example, to ensure patient safety we initially paused enrollment of our sotorasib Phase 1 combination cohort with Keytruda[®] and Phase 3 lung cancer study, and the interruption in enrollment may ultimately affect the timeline of these studies. Additionally, while we are investing in research and collaborations to potentially develop treatments for COVID-19, such activities may not result in therapeutic candidates, product approvals and/or significant commercial value being derived from potential COVID-19-related medicines.

We have experienced, and expect to continue to experience, regulatory delays, including delays in receiving regulatory advice, reviews of applications, or performance of inspections required for approvals as a result of the COVID-19 pandemic. The pandemic may also result in greater regulatory uncertainty. For example, the FDA and the European Medicines Agency have issued guidance to provide biopharmaceutical manufacturers greater flexibility in certain regulatory areas, including protocol deviations and adverse event reporting. However, such flexibility may result in greater uncertainty regarding the expectations of such health authorities in relation to this guidance, including uncertainty regarding the expectations of health authorities in connection with the development of treatments for COVID-19. Additionally, there may be delays in ongoing or new patent office or court patent proceedings in the U.S. or internationally that may delay the outcome of such proceedings. Such delays and disruptions could have a significant adverse effect on our product development and launches, product sales, business and results of operations.

In response to COVID-19, we have activated our applicable business continuity plans, including suspending U.S. in-person meetings and interactions with the healthcare community and professionals in a substantial number of states, suspending, as a general matter, all international business travel and the majority of domestic travel within the United States, and U.S. employees who are able to work from home have been doing so since mid-March 2020. Our ability to perform critical functions and maintain operations could be adversely affected as a result of such workforce restrictions, and the COVID-19-related support programs we have put into place for our staff, suppliers and customers are increasing our operating expenses and reducing the efficiency of our operations. Notwithstanding such support programs, the COVID-19 pandemic could affect the health and availability of our workforce as well as those of the third parties on which we rely. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to COVID-19, we may not be able to execute on our business strategy and our operations may be adversely affected. We may also experience limitations of employee resources, including as a result of illness of employees or their families. Additionally, disruptions in public and private infrastructure, including transportation and supply chains, have further adversely affected the efficiency of our business operations. Also, the transition of the majority of our workforce to a remote work environment in response to COVID-19, as well as that of our third-party service providers, may exacerbate certain risks to our business, including, but not limited to, an increased demand for information technology resources, increased risk of cybersecurity attacks (including social engineering attacks), and increased risk of unauthorized dissemination of sensitive personal information or our proprietary or confidential information. As the pandemic progresses, we have observed an increase in cybersecurity incidents, predominantly ransomware and social engineering attacks, experienced by our third-party service providers. Such third-party incidents have created the risk of the loss of availability of information (including information related to our clinical trials) important to the operation of our business. For example, in April 2020 and in September 2020, vendors that provide us with information technology services and clinical data services, respectively, each experienced a ransomware attack that required us to disconnect our systems from those vendors. While we do not believe these cybersecurity incidents have had a significant adverse effect on our operations, an extended service outage, particularly where a vendor is the single source from which we obtain services, or where a cybersecurity incident significantly affects the operation of our own systems, could have a material adverse effect on our business. In the future, as the pandemic progresses and afterwards, we may experience significant adverse effects on our commercial and clinical manufacturing activities, our operations, and our cybersecurity, and our suppliers and vendors may also experience significant disruptions to their activities and operations on which we depend, as a result of these cybersecurity incidents.

Federal, state and local, and international governmental policies and initiatives designed to reduce the transmission of COVID-19 also have resulted in the cancellation of diagnostic, elective, specialty and other procedures and appointments to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19. These measures and challenges will likely continue to varying degrees for the duration of the pandemic, which is uncertain, and have significantly reduced patient access to and administration of certain of our drugs. For example, Prolia[®] is a product requiring administration by a healthcare provider in doctors' offices or other healthcare settings that are affected by COVID-19. The U.S. label for Prolia[®] instructs healthcare professionals who discontinue Prolia[®] to transition the patient to an alternative antiresorptive, including oral treatments that do not require administration by a healthcare provider. Further, as a result of COVID-19, oncology patients, in consultation with their doctors, may be selecting less immunosuppressive therapies or therapies that do not require administration in a hospital setting, potentially adversely affecting certain of our products. New patients are less likely to be diagnosed and/or to start therapeutics during the pandemic. Once the pandemic subsides, we anticipate there will be a substantial backlog of patients seeking appointments with physicians relating to a variety of medical conditions, and as a result, patients seeking treatment with certain of our products may have to navigate limited provider capacity, and this limited provider capacity could have a continued adverse effect on our sales following the opening up of various geographies and/or the end of the pandemic. Further, the effects of the COVID-19 pandemic may result in long-term shifts in preferences among healthcare professionals and patients toward treatments that do not require administration by healthcare professionals or visits to medical facilities.

The legislative and regulatory environment governing our businesses is dynamic and changing frequently in response to COVID-19. More than a dozen states have taken action to help patients maintain access to prescription drugs during the COVID-19 pandemic including requiring state-regulated commercial plans to cover 90-day fills and emergency fills in certain circumstances. At the federal level, there have been legislative and administrative proposals seeking to incentivize greater drug manufacturing in the United States with the stated goal of improving supply reliability in the United States. For example, on August 6, 2020, the Administration issued an Executive Order aimed at boosting domestic production of essential medicines, medical countermeasures, and critical inputs titled “Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs are Made in the United States.” Additionally, one legislative proposal would prohibit the U.S. Department of Veterans Affairs from purchasing certain drugs that have active pharmaceutical ingredients manufactured outside the United States. While we perform a substantial majority of our commercial manufacturing activities in the United States, including in the U.S. territory of Puerto Rico, and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California, the passage of such legislation could result in foreign governments enacting retaliatory legislation or regulatory actions, which may have an adverse effect on our product sales, business and results of operations. The COVID-19 pandemic has also resulted in increased interest in compulsory licenses, march-in rights or other governmental interventions, both in the United States and internationally, related to the procurement of drugs, such as the WHO’s COVID-19 Technology Access Pool initiative, which provides an approach for sharing all intellectual property, information and clinical trial data necessary to enable generic drug manufacturing. Pursuant to the declaration of a national emergency in March 2020 under the Stafford Act, state and local governments may request access to discounted pricing for certain items related to the COVID-19 response. The CARES Act implements initiatives to provide advanced payments from Medicare to healthcare providers, clinics and physicians and to require Medicare plans to provide up to a 90-day supply of Part D drugs. However, despite such initiatives and government support, there may be adverse effects on the timing and collectability of our customer receivables as a result of the COVID-19 pandemic. See our Annual Report on Form 10-K for the year ended December 31, 2019, Part I, Item 1A. Risk Factors—*Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively affect our business*. The COVID-19 pandemic has also resulted in a significant increase in unemployment and underemployment in the United States which may continue after the pandemic. Such a significant increase in unemployment or other disruptions in the labor market are expected to lead to a substantial reduction in disposable income and access to healthcare insurance, including reductions in the commercially insured population that lead to growth in Medicaid enrollment, which could adversely affect our product sales. Such reduction in healthcare insurance could be compounded by any full or partial repeal of the Affordable Care Act by the U.S. Supreme Court. Further, the substantial pressures placed on governmental and payor budgets as a result of the COVID-19 pandemic and the projected governmental budget shortfalls caused by significantly reduced economic activity during and potentially after the COVID-19 pandemic may result in greater and continued downward price pressure on biopharmaceutical products and increased intensity of stakeholder negotiations across the biopharmaceutical value chain. For example, on July 24, 2020, the Administration announced a number of Executive Orders intended to reduce the cost of biopharmaceuticals for patients. On September 13, 2020 the Administration subsequently released the text of its Executive Order for a “most favored nation” policy for Medicare Parts B and D, under which the U.S. Department of Health and Human Services (HHS) is directed to take steps to implement payment models that set Medicare purchase prices based on the lowest price available in economically comparable countries for certain, yet to be determined, Part B and Part D medicines. On September 24, 2020 HHS released a final rule to allow states (or other non-federal government entities) to submit proposals to the FDA allowing for the importation of certain prescription drugs from Canada. On September 30 and October 1, 2020, the House Oversight and Reform Committee held hearings with executives from several pharmaceutical companies, including Amgen, with a focus on drug pricing practices. Drug pricing scrutiny also continues at the state level. These Executive Orders, rules and other activities have the potential to increase the risks described and discussed in our Annual Report on Form 10-K for the year ended December 31, 2019, Part I, Item 1A. Risk Factors—*Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability*, and such risks could materially adversely affect our product sales, business, profitability, results of operations, cash flows and financial position. Further, while the outcome of the November U.S. elections may result in some changes to the legislative, regulatory and administrative proposals governing our business, we expect continued significant focus on healthcare and drug pricing proposals beyond the election.

The global spread of COVID-19 has also led to disruption and volatility in the global capital markets. We have certain assets, including equity investments, that are exposed to market fluctuations that could, in a sustained or recurrent series of market disruptions, result in impairments. Further, the economic downturn resulting from this global pandemic has precipitated a global recession which may be of an extended duration. See our Annual Report on Form 10-K for the year ended December 31, 2019, Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business*.

As the pandemic continues, and if conditions worsen or if the duration of the pandemic extends significantly, we expect to experience additional adverse effects on our operational and commercial activities, customer purchases and our collections of accounts receivable. It is unclear which adverse effects may be material, and it remains uncertain the degree to which these adverse effects would impact our future operational and commercial activities, customer purchases and our collections even if conditions begin to improve. The lifting or reduction of restrictions on business operations and in-person gatherings has led to a resurgence in COVID-19 infections in numerous jurisdictions, resulting in the reinstatement of stricter restrictions and shutdowns. It is expected that there will be an ebb and flow to the pandemic with different jurisdictions having higher levels of infections than others over the course of the pandemic. In addition to existing travel restrictions, jurisdictions may continue or reinstate border closures, impose or reimpose prolonged quarantines and further restrict travel and business activity, which could significantly affect our ability to support our operations and customers and the ability of our employees to get to their workplaces to discover, study, develop and produce our product candidates and products, disrupt the movement of our products through the supply chain, and prevent or discourage patients from seeking healthcare services and the administration of certain of our products. Further, in connection with the global outbreak and spread of COVID-19 and in an effort to increase the wider availability of needed medical products, we or our suppliers may elect to, or governments may require us or our suppliers to, allocate manufacturing capacity (for example pursuant to the U.S. Defense Production Act) in a way that adversely affects our regular operations, customer relationships and financial results. The rapid reallocation of resources for the treatment and prevention of COVID-19, including the production of COVID-19 vaccinations or related therapies, could also result in increased competition for, or reduced availability of, materials used in the manufacturing or distribution of our products. In addition, unpredictable increases in demand for certain of our products could exceed our capacity to meet such demand, which could adversely affect our financial results and customer relationships.

The COVID-19 pandemic and the volatile global economic conditions stemming from it may precipitate or amplify the other risks described in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2019, which could materially adversely affect our business, operations and financial conditions and results. For example, if a natural disaster or other potentially disruptive event occurs concurrently with the COVID-19 pandemic, such disaster or event could deplete our inventory levels and we could experience a disruption to our manufacturing or ability to supply our products. Further, the global pandemic has exacerbated geopolitical tensions, and some countries, such as China, may be especially vulnerable to such dynamics. If relations between the U.S. and China or other governments deteriorates, our business and investments in China or other such markets may also be adversely affected.

The rapid development and fluidity of the pandemic preclude any prediction as to the ultimate effect of COVID-19 on us. The duration of the measures being taken by the authorities to mitigate against the spread of COVID-19, and the extent to which such measures are effective, if at all, remain highly uncertain. We believe the magnitude and degree of COVID-19’s adverse effect on our product development, product sales, businesses, operating results, cash flows and financial condition will be driven by the severity and duration of the pandemic, the pandemic’s effect on the United States and global economies and the timing, scope and effectiveness of federal, state, local and international governmental responses to the pandemic. If the spread continues at or near its current trajectory or mitigation continues to require similar levels of shelter-in-place and shut-down orders, any adverse effects of COVID-19 will likely grow and could be enduring and our product development, product sales, business, results of operations, cash flows and financial position could be materially adversely affected.

The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability.

We are subject to income and other taxes in the United States and other jurisdictions in which we do business. As a result, our provision for income taxes is derived from a combination of applicable tax rates in the various places we operate. Significant judgment is required for determining our provision for income tax.

Our tax returns are routinely examined by tax authorities in the United States and other jurisdictions in which we do business, and a number of audits are currently underway. Tax authorities, including the Internal Revenue Service (IRS), are becoming more aggressive in their audits and are particularly focused on the allocations of income and expense among tax jurisdictions. In April 2017, we received an RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposed to make significant adjustments that primarily relate 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 calculations but continues to propose substantial adjustments. We disagree with the proposed adjustments and the matter is currently within the jurisdiction of the IRS administrative appeals office. If we are unable to reach resolution, we will vigorously contest the proposed adjustments through the judicial process. In addition, in May 2020, we received an RAR from the IRS for the years 2013, 2014 and 2015 proposing adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. In September 2020, we received a revised RAR that continues to propose substantial adjustments for the years 2013, 2014 and 2015. We disagree with the proposed adjustments and calculations, and will pursue resolution with the IRS administrative

appeals office. Final resolution of these complex matters is not likely within the next 12 months and could require us to go through the judicial process to resolve. 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 substantially greater than amounts accrued and could have a material negative impact on our condensed consolidated financial statements.

Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities and changes in applicable tax laws, regulations or administrative interpretations thereof. The Tax Cuts and Jobs Act (the 2017 Tax Act) is complex and a large volume of regulations and guidance has been issued to date and could be subject to different interpretations. We could face audit challenges to our application of the new law that could have a negative effect on our provision for income taxes. A change to the U.S. tax system, such as a repeal or modification of the 2017 Tax Act, a change to the tax system in a jurisdiction where we have significant operations, such as the U.S. territory of Puerto Rico, or changes in tax law in the United States or other jurisdictions where we do business, could have a material and adverse effect on our business and on the results of our operations.

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

During the three months ended September 30, 2020, we had one outstanding stock repurchase program, under which the repurchase activity was as follows:

Period	Total number of shares purchased	Average price paid per share ⁽¹⁾	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program ⁽²⁾
July 1 - 31	1,069,984	\$ 252.92	1,069,984	\$ 4,678,996,437
August 1 - 31	1,004,844	\$ 242.72	1,004,844	\$ 4,435,099,357
September 1 - 30	960,100	\$ 246.50	960,100	\$ 4,198,437,082
Total	3,034,928	\$ 247.51	3,034,928	

⁽¹⁾ Average price paid per share includes related expenses.

⁽²⁾ In December 2019, our Board of Directors increased the amount authorized under our stock repurchase program by an additional \$4.0 billion.

Item 6. EXHIBITS

Reference is made to the Index to Exhibits included herein.

INDEX TO EXHIBITS

Exhibit No.	Description
2.1	Asset Purchase Agreement, dated August 25, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.2	Amendment No. 1 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on October 17, 2019 and incorporated herein by reference.)
2.3	Amendment No. 2 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.4	Letter Agreement, dated November 21, 2019, by and between Amgen Inc. and the parties named therein re: Treatment of Certain Product Inventory in connection with Amgen's acquisition of Otezla. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.5	Irrevocable Guarantee, dated August 25, 2019, by and between Amgen Inc. and Bristol-Myers Squibb Company. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value \$.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.6	Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.7	Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.8	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.9	Officers' Certificate of Amgen Inc., dated May 30, 2007, including form of the Company's 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 form of the Company's 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 form of the Company's 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 form of the Company's 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 form of the Company's 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 form of the Company's 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 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 form of the Company's 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 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 form of the Company's 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 form of the Company's 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 2.700% 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 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 form of the Company's 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 herein by reference.)
- 4.29 [Officer's Certificate of Amgen Inc., dated as of February 21, 2020, including forms of the Company's 1.900% Senior Notes due 2025, 2.200% Senior Notes due 2027, 2.450% Senior Notes due 2030, 3.150% Senior Notes due 2040 and 3.375% Senior Notes due 2050.](#) (Filed as an exhibit to Form 8-K on February 21, 2020 and incorporated herein by reference.)
- 4.30 [Officer's Certificate of Amgen Inc., dated as of May 6, 2020, including form of the Company's 2.300% Senior Notes due 2031.](#) (Filed as an exhibit to Form 8-K on May 6, 2020 and incorporated herein by reference.)
- 4.31 [Officer's Certificate of Amgen Inc., dated as of August 17, 2020, including forms of the Company's 2.770% Senior Notes due 2053.](#) (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)

- 4.32 [Registration Rights Agreement, dated as of August 17, 2020, by and among Amgen Inc., BofA Securities, Inc. and J.P. Morgan Securities LLC, as lead dealer managers, and BNP Paribas Securities Corp., Deutsche Bank Securities Inc., RBC Capital Markets, LLC, Blaylock Van, LLC and Siebert Williams Shank & Co., LLC, as co-dealer managers.](#) (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)
- 10.1+ [Amgen Inc. Amended and Restated 2009 Equity Incentive Plan.](#) (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
- 10.2+ [First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015.](#) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.)
- 10.3+ [Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016.](#) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)
- 10.4+ [Form of Grant of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. \(As Amended on December 10, 2019.\)](#) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
- 10.5+ [Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. \(As Amended on December 10, 2019.\)](#) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 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. \(As Amended on December 10, 2019.\)](#) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
- 10.8+ [Amgen Inc. 2009 Director Equity Incentive Program. \(As Amended on December 11, 2019.\)](#) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 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. \(As Amended on December 11, 2019.\)](#) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
- 10.11+ [Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program. \(As Amended on December 11, 2019.\)](#) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 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+ [Second Amendment to the Amgen Inc. Supplemental Retirement Plan \(As Amended and Restated effective October 23, 2019.\)](#) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
- 10.15+ [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.)
- 10.16+ [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.)
- 10.17+ [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.)

- 10.18+ [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.)
- 10.19+ [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.)
- 10.20+ [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.)
- 10.21+ [Second Amendment to the Amgen Nonqualified Deferred Compensation Plan \(As Amended and Restated effective January 1, 2020.\)](#) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
- 10.22+ [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.)
- 10.23+ [Agreement between Amgen Inc. and Peter Griffith, dated October 18, 2019.](#) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)
- 10.24 [Second Amended and Restated Credit Agreement, dated December 12, 2019, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent.](#) (Filed as an exhibit to Form 8-K on December 12, 2019 and incorporated herein by reference.)
- 10.25 [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.)
- 10.26 [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.)
- 10.27 [Letter Agreement, dated June 25, 2019, by and between Amgen Inc. and UCB Celltech](#) (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2019 on July 31, 2019 and incorporated herein by reference.)
- 10.28 [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.)
- 10.29 [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.)
- 10.30 [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.)
- 10.31 [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.)
- 10.32 [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.)
- 10.33 [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.)

- 10.34 [Side Letter Regarding Collaboration Agreement and Stivarga Agreement, dated February 13, 2020, by and between Onyx Pharmaceuticals, Inc. and Bayer HealthCare LLC.](#) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 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.)
- 10.41* [Amendment No. 2 to the Collaboration Agreement, dated August 19, 2020, by and between Amgen Inc. and Novartis Pharma AG](#) (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.)
- 10.42 [Collaboration Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene Switzerland GmbH, a wholly-owned subsidiary of BeiGene, Ltd.](#) (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
- 10.43 [Guarantee, dated as of October 31, 2019, made by and among BeiGene, Ltd. and Amgen Inc.](#) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
- 10.44 [Share Purchase Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene, Ltd.](#) (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
- 10.45 [Amendment No. 1 to Share Purchase Agreement, dated December 6, 2019, by and among BeiGene, Ltd. and Amgen Inc.](#) (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
- 10.46* [Restated Amendment No. 2 to Share Purchase Agreement, dated September 24, 2020, by and among BeiGene, Ltd. and Amgen Inc.](#)
- 10.47 [Collaboration Agreement dated March 30, 2012 by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, a wholly owned subsidiary of AstraZeneca Pharmaceuticals LP](#) (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, 2012 on May 8, 2012 and incorporated herein by reference.)

10.48	Amendment No. 1 to the Collaboration Agreement, dated October 1, 2014, by and among Amgen Inc., AstraZeneca Collaboration Ventures, LLC and AstraZeneca Pharmaceuticals LP (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, 2014 on February 19, 2015 and incorporated herein by reference.)
10.49	Amendment Nos. 2 through 6 to the March 30, 2012 Collaboration Agreement between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, dated May 2 and 27 and October 2, 2016, January 31, 2018, and May 15, 2020, respectively (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2020 on July 29, 2020 and incorporated herein by reference.)
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

(* = filed herewith)

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

(+ = management contract or compensatory plan or arrangement)

SIGNATURES

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

Amgen Inc.
(Registrant)

Date: October 28, 2020

By:

/s/ PETER H. GRIFFITH
Peter H. Griffith
Executive Vice President and Chief Financial Officer
(Principal Financial 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 “[*]”.

AMENDMENT No.2
to the Collaboration Agreement

between Novartis Pharma AG and Amgen Inc.

This Amendment No. 2 (this “**Amendment**”) is entered into as of August 19, 2020, by and between Amgen Inc. (“**Amgen**”) and Novartis Pharma AG (“**Novartis**”). Each of the parties is referred to herein as a “**Party**” and collectively as the “**Parties**”.

WHEREAS, Novartis and Amgen are parties to a Collaboration Agreement dated as of April 21, 2017, as amended (the “**Collaboration Agreement**”) with respect to the Commercialization of and Medical Affairs Activities for the Product in the United States;

WHEREAS, the Parties mutually desire to amend, modify and restate certain terms and conditions of the Collaboration Agreement regarding the Commercialization of the Product;

NOW THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, the Parties hereto agree as follows:

1. **DEFINITIONS.** Unless otherwise defined herein, capitalized words in this Amendment shall have the meaning attributed to them in the Collaboration Agreement.
2. **AMENDMENTS.** The Parties agree that, as of April 1, 2020, the Collaboration Agreement is amended as follows:
 - a. Section 1.36 of the Collaboration Agreement is deleted in its entirety and replaced with the following:

1.36 “*Detail*” means an interactive, one-on-one, meeting (via face-to-face, teleconference, or videoconference) in an individual or group practice setting, between one or more healthcare professionals having prescribing authority and one Amgen or Novartis (or their respective Affiliates) sales representative during which uses, safety, effectiveness, contraindications, side effects, warnings or other relevant characteristics of the Product are discussed in an effort to increase prescribing preferences of the Product for its approved uses. Details will not include (i) activities conducted by medical support staff (such as Medical Liaisons) or (ii) unless the Parties otherwise mutually agree in writing, activities conducted at conventions or similar gatherings and activities performed by market development specialists, managed care account directors and other personnel not performing interactive sales calls or not specifically trained with respect to a pharmaceutical product. When used as a verb, “Detail” or “Detailing” shall mean to engage in a Detail.

b. Section 8.6.5 of the Collaboration Agreement is deleted in its entirety and replaced with the following:

8.6.5 Calculation of Sales Force Costs. Sales Force Costs for each of the Parties in the United States for a given Calendar Quarter will be determined by including in Commercialization Costs, for the respective Party, the lesser of, for each of specialty and non-specialty sales forces, (a) the applicable quarterly budget cap for the Sales Force Costs for such Party (as calculated in Appendix A) and (b) the Sales Force FTE Costs of Details (as calculated in Appendix A) performed by such Party or any of its Affiliates or contractors in the United States utilizing a First Position Detail Equivalent Basis as follows: (i) [*] percent ([*]%) if such sales representative Details the Product as a First Position Detail as set forth in the Commercialization Plan and details no other products; (ii) [*] percent ([*]%) if such sales representative Details the Product as the First Position Detail as set forth in the Commercialization Plan and details only one (1) other product; (iii) [*] percent ([*]%) if such sales representative Details the Product as a First Position Detail as set forth in the Commercialization Plan and details only [*] ([*]) other products; (iv) [*] percent ([*]%) if such sales representative Details the Product as a Second Position Detail and details only [*] ([*]) or [*] ([*]) other product(s); and (v) [*] percent ([*]%) [*] other products ((i) through (v), as applicable, the “*First Position Detail Equivalent Basis*”). Notwithstanding the foregoing, in case the Parties agree that the Detailing under this Agreement, for any given Calendar Quarter, shall be or has been significantly impacted such that each Party’s call plan under the Commercialization Plan will not be achieved due to causes beyond each Party’s reasonable control, which shall include pandemics and other outbreak of illness or public health events, (A) the amount corresponding to the foregoing sub-clause (a) shall be deemed the applicable Sales Force Costs for each of the Parties for inclusion into the Commercialization Costs or (B) the determination of each Party’s applicable Sales Force Costs shall be handled as may otherwise be agreed upon by the Parties in writing.

3. **RETROACTIVE APPLICATION.** This Amendment shall become effective retroactively as of April 1, 2020, and the terms and conditions of the Agreement, as modified by this Amendment, shall apply onward from April 1, 2020 and, for clarity, shall apply to the calculation of Sales Force Costs for the second Calendar Quarter of 2020.

4. **INTEGRATION.** Except for the sections of the Collaboration Agreement specifically amended hereunder, all terms and conditions of the Collaboration Agreement remain and shall remain in full force and effect. This Amendment shall hereafter be incorporated into and deemed part of the Collaboration Agreement and any future reference to the Collaboration Agreement shall include the terms and conditions of this Amendment.

5. **APPLICABLE LAW & JURISDICTION.** This Amendment shall be governed by, and construed in accordance with, the laws which govern the Collaboration Agreement, and the Parties submit to the jurisdiction and dispute resolution provisions as set forth in the Collaboration Agreement.

6. **COUNTERPARTS.** This Amendment may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument. Signature pages of this Amendment may be exchanged by facsimile or other electronic means without affecting the validity thereof.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the authorized representative of each of the Parties hereto has caused this Amendment to be executed as of the date first above written.

AMGEN INC.

By: /s/ Carly Baron

Name: Carly Baron

Title: Vice President GM Neuroscience

NOVARTIS PHARMA AG

By: /s/ Peter Macaskill

Name: Peter Macaskill

Title: Global Marketing Executive Director

By: /s/ Shusaku Iwasaki

Name: Shusaku Iwasaki

Title: Senior Legal Counsel

[Signature Page to Amendment No. 2 to Collaboration Agreement]

Pursuant to Regulation S-K, Item 601(a)(5), Appendix A to Amendment No. 2 to Collaboration Agreement, as listed below, has not been filed. The Registrant agrees to furnish supplementally a copy of any omitted appendices to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.

Appendix A

Illustrative Example of:

- Calculation of Applicable Quarterly Budget Cap for Sales Force Costs
- Calculation of Sales Force FTE Costs of Details

BEIGENE, LTD.

RESTATED AMENDMENT NO. 2 TO SHARE PURCHASE AGREEMENT

THIS RESTATED AMENDMENT NO. 2 (this “**Amendment**”) to the SHARE PURCHASE AGREEMENT, dated as of October 31, 2019, as amended on December 6, 2019 (the “**Agreement**”), is made and entered into as of September 24, 2020, by and among BeiGene, Ltd., an exempted company incorporated in the Cayman Islands (the “**Company**”), and Amgen Inc., a Delaware corporation (the “**Investor**”), and restates in its entirety the Amendment No. 2 to the Agreement dated March 17, 2020. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Agreement.

RECITALS

WHEREAS, pursuant to the Agreement, the Investor purchased and subscribed for Two Hundred Six Million Six Hundred Thirty-Five Thousand Thirteen (206,635,013) Ordinary Shares in the form of Fifteen Million Eight Hundred Ninety-Five Thousand One (15,895,001) American Depositary Shares of the Company at a purchase price of \$13.45 per share, or \$174.85 per American Depositary Share, at the Closing, which represented approximately twenty point five percent (20.5%) of the Company’s outstanding share capital as of that date and, pursuant to the Agreement, subsequent to the Closing, the Investor has purchased additional American Depositary Shares of the Company to account for dilution and maintain the Investor’s ownership interest;

WHEREAS, in order to continue to account for periodic dilution from the issuance of the Company’s shares under its equity incentive plans, the Company and the Investor would like to provide for the option to purchase by the Investor of such supplemental amount of American Depositary Shares of the Company on a monthly basis such that the Investor will hold approximately twenty point six percent (20.6%) of the Company’s outstanding share capital immediately following each such purchase in support of the maintenance of the Investor’s equity method accounting treatment for its investment in the Company;

WHEREAS, pursuant to Section 8.9 of the Agreement, no provision in the Agreement may be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the Investor and the Company; and

WHEREAS, the Company will seek all approvals of the Company’s shareholders required for the Company to (i) enter into this Amendment and (ii) issue the Monthly Firm Shares (as defined below), in each case in accordance with the HK Listing Rules.

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. **Addition of Section 2.4.** The following shall be inserted as a new Section 2.4 of the Agreement:

“2.4 Monthly Sale of Additional Shares.

(a) Subject to the Subsequent Shareholder Approval and the Annual Shareholder Approvals, purchases and sales under this Section 2.4 shall commence on the first (1st) day of the month following the Subsequent Shareholder Approval (or if the Company’s American Depositary Shares are not trading on NASDAQ on such day, the next trading day) (the “**Commencement Date**”) and shall continue until the earliest of (i) the date on which the Investor and its Affiliates collectively own less than twenty percent (20%) of the outstanding share capital of the Company as a result of the Investor’s sale of Shares, (ii) written notice from either the Investor or the Company that such party wishes to terminate such monthly purchases and sales, which notice shall be provided at least sixty (60) days in advance of the termination of such monthly purchases and sales or, if requested by the Investor, such longer period as reasonably required, upon advice of Investor’s counsel, to permit the Investor to commence market purchases under a trading plan in accordance with Rule 10b5-1 under the Exchange Act, and (iii) the third anniversary of the Commencement Date (the “**Monthly Sale Period**”). Upon mutual agreement by the parties and subject to approval by the Company’s shareholders if required by the HK Listing Rules, this Amendment shall be extended for additional three-year terms upon expiration of the then current term.

(b) During the Monthly Sale Period, on the first (1st) day of each month (or if the Company’s American Depositary Shares are not trading on NASDAQ on such day, the next trading day), the Company shall send or cause to be sent via e-mail to the Investor the following information (such notice, the “**Monthly Firm Shares Notice**”): (i) the number of ADSs Outstanding and number of Non-Equity Incentive Shares, each as of the applicable Reference Date, (ii) the Amgen Holding and Amgen Percentage as of such Reference Date based on the latest information provided by the Investor (which shall be confirmed by the Investor and revised if inaccurate), (iii) the volume weighted average price of one Company American Depositary Share on NASDAQ for the ninety (90) calendar days preceding such Reference Date, as reported by Bloomberg (each, a “**Monthly Firm Shares Purchase Price**”) and (iv) an updated Company Disclosure Schedule as of the applicable Reference Date in accordance with Section 2.4(d), if any. If the Amgen Percentage is less than the Trigger Percentage as of such Reference Date, then, upon the Investor’s written request (the “**Investor Request**”) delivered within two (2) Business Days following Investor’s receipt of the Monthly Firm Shares Notice, the Company hereby agrees to sell to the Investor and the Investor agrees to subscribe for such additional number of Ordinary Shares in the form of American Depositary Shares (the “**Monthly Firm Shares**”) calculated pursuant to the following formula:

$$X = (((A-B)*C)-D) / (1-C)$$

X = the number of Monthly Firm Shares expressed in ADSs

A = the number of ADSs Outstanding

B = the number of Non-Equity Incentive Shares

C = 20.6%

D = the Amgen Holding,

at a purchase price per Monthly Firm Share equal to the Monthly Firm Shares Purchase Price; *provided, however*, that in no event shall the aggregate number of Monthly Firm Shares issued during the Monthly Sale Period, exceed Seventy-Five Million (75,000,000) Ordinary Shares (subject to appropriate adjustment in the event of any share dividend, share split, combination or other similar recapitalization with respect to the Ordinary Shares). If the Amgen Percentage in any such Monthly Firm Shares Notice is equal to or greater than the Trigger Percentage, then the Investor shall not have the option to subscribe for, and the Company shall not issue, any Monthly Firm Shares for such month. The Monthly Firm Shares shall be in the form of American Depositary Shares, unless the Investor requests in writing that the Monthly Firm Shares be delivered in the form of Ordinary Shares, in which case the number of shares and purchase price shall be adjusted accordingly based on the ADS to Ordinary Share ratio. Any Monthly Firm Shares purchased hereunder shall be “Shares” or “Deposit Shares” as the context shall so require for purposes of Article 1, Article 3, Article 4, Article 5 and Article 8 of the Agreement. Until such time as the Investor elects to cease equity method accounting for its investment in the Company, subject to the Annual Shareholder Approvals, the Investor and Company acknowledge and agree that the Investor’s direct purchase of Ordinary Shares in the form of American Depositary Shares from the Company on a monthly basis hereunder shall be the primary means for the Investor to purchase shares in order to maintain such equity method accounting treatment.

(c) Subject to the terms and conditions hereof, the closing of the purchase and sale of Monthly Firm Shares, if any, shall take place each month within seven (7) Business Days following the Reference Date, or at such other time as mutually agreed by the Company and the Investor (the “**Monthly Closing**”). At each Monthly Closing, the Company will instruct the Transfer Agent to deliver to the Investor, via book entry to the applicable balance account registered in the name of the Investor, the Monthly Firm Shares for such month, against payment of the aggregate Monthly Firm Share Purchase Price for such Monthly Firm Shares in U.S. dollars by wire transfer of immediately available funds to the order of the Company.

(d) For purposes of Article 3 and Article 4 of the Agreement, the representations and warranties contained therein shall be deemed made as of the date of the applicable Monthly Closing, as supplemented by, in the case of Article 3, (i) the Company’s most recent Form 10-K (including any information incorporated by reference therein from the Company’s definitive proxy statement on Schedule 14A) and any subsequent Form 10-Q and Form 8-K filed with or furnished to the SEC and made publicly available prior to the date of delivery of the Monthly Firm Shares Notice (other than (x) any information that is contained in the “Risk Factors” or “Note Regarding Forward-Looking Statements” or similar sections of such Company SEC Documents and (y) any forward-looking statements, or other statements that are

similarly predictive or forward-looking in nature, contained in such Company SEC Documents), and (ii) any update to the Company Disclosure Schedule as of the applicable Reference Date provided by the Company to Investor in accordance with Section 2.4(b); provided that the Company shall not be required to provide any updates to (x) Section 3.2 (Subsidiaries) to list any newly formed subsidiaries since the most recent disclosures in the Form 10-K or any Form 10-Q, or (y) Section 3.3 (Capitalization) other than providing the updated number of outstanding shares included in the Monthly Firm Shares Notice, which shall constitute a representation and warranty of the Company under the Agreement as to such number of outstanding shares; and provided, further, that if there are any material updates to the Company Disclosure Schedule following delivery of the Investor Request, the Investor Request may be revoked prior to the issuance of the shares in the Investor's sole discretion.

(e) For purposes of this Section 2.4:

(i) “**ADS**” means American Depositary Shares.

(ii) “**ADSs Outstanding**” means the total number of the Company's Ordinary Shares outstanding prior to NASDAQ market opening on the Reference Date, expressed in terms of ADSs.

(iii) “**Amgen Holding**” means the number of the ADSs Outstanding held by the Investor as of the latest Reference Date.

(iv) “**Amgen Percentage**” means the percentage of the ADSs Outstanding held by the Investor as of the latest Reference Date.

(v) “**Annual Shareholder Approvals**” means, following the Subsequent Shareholder Approval, the annual approvals of the Company's shareholders required for the Company to continue issuing the Monthly Firm Shares during the term of this Agreement in accordance with the conditions of the waiver granted by The Stock Exchange of Hong Kong Limited (the “**HK Stock Exchange**”) on August 10, 2020 from the requirements of Rules 13.36(1)(a) and 14A.36 of the HK Listing Rules.

(vi) “**Non-Equity Incentive Shares**” means the aggregate number of shares issued other than upon exercise, vesting or issuance of share options, restricted shares, restricted share units, Ordinary Shares or ADSs, or other equity incentives to employees, consultants and directors of the Company since the Commencement Date, expressed in terms of ADSs; provided, however, that (x) if the Investor exercised its participation right pursuant to Section 5.16(a) in whole or in part in an offering (subject to applicable Law, HK Listing Rules and any waiver therefrom granted by the HK Stock Exchange) or (y) if the Investor purchased Ordinary Shares (expressed in terms of ADSs) or ADSs through a trading plan in accordance with Rule 10b5-1 under the Exchange Act or otherwise purchased Ordinary Shares (expressed in terms of ADSs) or ADSs from any Person other than the Company, then such shares issued in such Non-Equity Incentive Share offering(s) shall not be deemed as Non-Equity Incentive Shares to the extent Investor's purchases pursuant to clauses (x) and (y) were made in response to the pro rata dilution to the Investor from such Non-Equity Incentive Share offerings.

(vii) “**Reference Date**” means the day on which the Company’s ADSs are trading on NASDAQ immediately preceding the first (1st) day of each calendar month during the Monthly Sale Period.

(viii) “**Subsequent Shareholder Approval**” means the approval of the Company’s shareholders required for the Company to (i) enter into Restated Amendment No. 2 to the Share Purchase Agreement and (ii) issue the Monthly Firm Shares in accordance with the HK Listing Rules.

(ix) “**Trigger Percentage**” means 20.4% of the Company’s outstanding share capital (expressed in terms of ADSs).”

2. Amendment to Section 5.16(a). The first sentence of Section 5.16(a) is deleted in its entirety and replaced with:

“If the Company proposes to offer or sell any Ordinary Shares, American Depositary Shares or Ordinary Share Equivalents after the Closing Date, other than pursuant to the Plans (“**New Securities**”), and at the time immediately prior to such offer or sale the Investor holds no more than twenty one percent (21.0%) of the Company’s outstanding share capital, the Company shall use reasonable best efforts to provide the Investor with an opportunity to participate in such offering or sale and purchase upon the same terms and conditions as other purchasers in the offering or sale of the New Securities, up to that portion of such New Securities as is necessary to allow the Investor to hold approximately twenty point six percent (20.6%) of the Company’s share capital after the sale of New Securities, so long as the Investor’s ownership percentage prior to such sale has not decreased as a result of the Investor’s sale of Shares or the Investor’s failure to participate in future offerings or sales of New Securities in which Investor is given the opportunity to participate pursuant to this Section 5.16(a), subject to applicable Law, HK Listing Rules and any waiver therefrom granted by the HK Stock Exchange.”

3. Addition of Section 5.21. The following shall be inserted as a new Section 5.21 of the Agreement:

“5.21 Preparation of Proxy; Shareholders Meeting; Board Recommendation.

(a) As promptly as reasonably practicable after the execution of this Amendment, the Company shall prepare and cause to be filed with the SEC and the HK Stock Exchange a proxy circular relating to the Subsequent Shareholder Approval (such proxy circular, and any amendments or supplements thereto, the “**Supplemental Proxy Statement**”). The Investor shall assist and cooperate with the Company in the preparation of the Supplemental Proxy Statement and the resolution of any comments to the Supplemental Proxy Statement received from the SEC or HK Stock Exchange. The Company shall promptly correct any information in the Supplemental Proxy Statement if and to the extent such information becomes false or misleading in any material respect. The Company shall notify the Investor upon the receipt of any comments from the SEC or HK Stock Exchange, as applicable, and of any request by the SEC or HK Stock Exchange, as applicable, for amendments or supplements to the Supplemental Proxy Statement. The Company shall use its reasonable best efforts to (i) respond as promptly as reasonably

practicable to any comments received from the SEC or HK Stock Exchange, as applicable, concerning the Supplemental Proxy Statement and to resolve such comments with the SEC or HK Stock Exchange, as applicable, and (ii) to cause the Supplemental Proxy Statement to be disseminated to its shareholders as promptly as reasonably practicable after the resolution of any such comments.

(b) The Company shall take all necessary actions in accordance with applicable Law, the governing documents of the Company and the rules of NASDAQ and the HK Stock Exchange, as applicable, to duly call, give notice of, convene and hold a special shareholders meeting (the “**Supplemental Meeting**”) for the purpose of obtaining the Subsequent Shareholder Approval, as soon as reasonably practicable after the SEC or HK Stock Exchange, as applicable, confirms that it has no further comments on the Supplemental Proxy Statement. Notwithstanding any provision of this Agreement to the contrary, the Company may adjourn, recess or postpone the Supplemental Meeting (i) to the extent necessary to ensure that any required supplement or amendment to the Supplemental Proxy Statement is provided to the shareholders of the Company within a reasonable amount of time in advance of the Supplemental Meeting, (ii) if as of the time for which the Supplemental Meeting is originally scheduled (as set forth in the Supplemental Proxy Statement) there are insufficient shares of capital stock of the Company represented (either in person or by proxy) to constitute a quorum necessary to conduct the business of the Supplemental Meeting or (iii) as may be required by applicable Law.”

4. General

A. Except as expressly modified by this Amendment, the terms and provisions of the Agreement shall remain unchanged and in full force and effect in accordance with its terms.

B. Each of the parties hereto shall bear its respective costs, including legal fees, and expenses incurred in connection with the preparation of this Amendment and the activities incurred in connection therewith.

C. This Amendment may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which shall constitute one and the same agreement.

D. This Amendment shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction.

E. The Agreement and this Amendment constitute the full and entire understanding and agreement between the Company and the Investor with regard to the subject matter hereof and neither the Company nor the Investor shall be liable or bound to any other in any manner by any representations, warranties, covenants and agreements except as specifically set forth herein and therein.

F. This Amendment shall become effective immediately upon execution by the Company and the Investor.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first written above.

THE COMPANY:

BEIGENE, LTD.

By: /s/ Scott A. Samuels

Name: Scott A. Samuels

Title: Senior Vice President, General Counsel

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first written above.

INVESTOR:

AMGEN INC.

By: /s/ Robert A. Bradway

Name: Robert A. Bradway

Title: Chairman of the Board, President & CEO

CERTIFICATIONS

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

1. I have reviewed this Quarterly Report on Form 10-Q of Amgen Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
 - (d) Disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 28, 2020

/s/ ROBERT A. BRADWAY

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

CERTIFICATIONS

I, Peter H. Griffith, Executive Vice President and Chief Financial Officer of Amgen Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Amgen Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
 - (d) Disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 28, 2020

/s/ PETER H. GRIFFITH

Peter H. Griffith

Executive Vice President and Chief Financial Officer

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 September 30, 2020 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 28, 2020

/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 September 30, 2020 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 28, 2020

/s/ PETER H. GRIFFITH

Peter H. Griffith

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.