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 AC 1934**

For the quarterly period ended September 30, 2021

or

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

Commission File Number: 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

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

(805) 447-1000
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value	**AMGN**	**The Nasdaq Stock Market LLC**
1.250% Senior Notes due 2022	**AMGN22**	**The Nasdaq Stock Market LLC**
2.00% Senior Notes due 2026	**AMGN26**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 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 28, 2021, the registrant had 563,265,902 shares of common stock, $0.0001 par value, outstanding.

AMGEN INC.

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Item 1. FINANCIAL STATEMENTS

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product sales	$ 6,320	$ 6,104	$ 18,026	$ 17,906
Other revenues	386	319	1,107	884
Total revenues	6,706	6,423	19,133	18,790
Operating expenses:				
Cost of sales	1,609	1,561	4,736	4,562
Research and development	1,422	1,062	3,471	2,978
Acquired in-process research and development	—	—	1,505	—
Selling, general and administrative	1,305	1,346	3,943	3,957
Other	(8)	1	143	162
Total operating expenses	4,328	3,970	13,798	11,659
Operating income	2,378	2,453	5,335	7,131
Other income (expense):				
Interest expense, net	(296)	(302)	(862)	(944)
Other income, net	73	55	97	69
Income before income taxes	2,155	2,206	4,570	6,256
Provision for income taxes	271	185	576	607
Net income	$ 1,884	$ 2,021	$ 3,994	$ 5,649
Earnings per share:				
Basic	$ 3.32	$ 3.45	$ 6.98	$ 9.61
Diluted	$ 3.31	$ 3.43	$ 6.93	$ 9.54
Shares used in calculation of earnings per share:				
Basic	567	585	572	588
Diluted	570	589	576	592

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Net income	$ 1,884	$ 2,021	$ 3,994	$ 5,649
Other comprehensive income (loss), net of reclassification adjustments and taxes:				
(Losses) gains on foreign currency translation	(35)	14	(60)	(41)
Gains (losses) on cash flow hedges	99	(128)	241	(305)
(Losses) gains on available-for-sale securities	(1)	1	(1)	(20)
Other	(3)	(7)	(3)	(9)
Other comprehensive income (loss), net of taxes	60	(120)	177	(375)
Comprehensive income	$ 1,944	$ 1,901	$ 4,171	$ 5,274

See accompanying notes.

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

	September 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,969	$ 6,266
Marketable securities	952	4,381
Trade receivables, net	4,765	4,525
Inventories	4,152	3,893
Other current assets	2,542	2,079
Total current assets	24,380	21,144
Property, plant and equipment, net	4,982	4,889
Intangible assets, net	14,659	16,587
Goodwill	14,665	14,689
Other noncurrent assets	6,307	5,639
Total assets	$ 64,993	$ 62,948
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,171	$ 1,421
Accrued liabilities	9,383	10,141
Current portion of long-term debt	4,288	91
Total current liabilities	14,842	11,653
Long-term debt	33,291	32,895
Long-term tax liabilities	6,483	6,968
Other noncurrent liabilities	2,160	2,023
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding—565.0 shares in 2021 and 578.3 shares in 2020	31,989	31,802
Accumulated deficit	(22,964)	(21,408)
Accumulated other comprehensive loss	(808)	(985)
Total stockholders' equity	8,217	9,409
Total liabilities and stockholders' equity	$ 64,993	$ 62,948

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, 2020	578.3	$ 31,802	$ (21,408)	$ (985)	$ 9,409
Net income	—	—	1,646	—	1,646
Other comprehensive income, net of taxes	—	—	—	152	152
Dividends declared on common stock ($1.76 per share)	—	—	(1,012)	—	(1,012)
Issuance of common stock in connection with the Company's equity award programs	0.7	6	—	—	6
Stock-based compensation expense	—	57	—	—	57
Tax impact related to employee stock-based compensation expense	—	(59)	—	—	(59)
Repurchases of common stock	(3.7)	—	(865)	—	(865)
Balance as of March 31, 2021	575.3	31,806	(21,639)	(833)	9,334
Net income	—	—	464	—	464
Other comprehensive loss, net of taxes	—	—	—	(35)	(35)
Issuance of common stock in connection with the Company's equity award programs	0.8	47	—	—	47
Stock-based compensation expense	—	100	—	—	100
Tax impact related to employee stock-based compensation expense	—	(76)	—	—	(76)
Repurchases of common stock	(6.5)	—	(1,592)	—	(1,592)
Other	—	—	5	—	5
Balance as of June 30, 2021	569.6	31,877	(22,762)	(868)	8,247
Net income	—	—	1,884	—	1,884
Other comprehensive income, net of taxes	—	—	—	60	60
Dividends declared on common stock ($1.76 per share)	—	—	(1,017)	—	(1,017)
Issuance of common stock in connection with the Company's equity award programs	—	9	—	—	9
Stock-based compensation expense	—	111	—	—	111
Tax impact related to employee stock-based compensation expense	—	(8)	—	—	(8)
Repurchases of common stock	(4.6)	—	(1,069)	—	(1,069)
Balance as of September 30, 2021	565.0	$ 31,989	$ (22,964)	$ (808)	$ 8,217

AMGEN INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)
(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 taxes	—	—	(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 CASH FLOWS
(In millions)
(Unaudited)

	Nine months ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net income	$ 3,994	$ 5,649
Depreciation, amortization and other	2,546	2,728
Deferred income taxes	(264)	(339)
Acquired in-process research and development	1,505	—
Other items, net	187	270
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	(269)	(31)
Inventories	(215)	(316)
Other assets	(373)	64
Accounts payable	(260)	(202)
Accrued income taxes, net	(719)	(301)
Long-term tax liabilities	102	110
Other liabilities	219	712
Net cash provided by operating activities	6,453	8,344
Cash flows from investing activities:		
Cash paid for acquisitions, net of cash acquired	(1,639)	—
Purchases of marketable securities	(8,901)	(5,329)
Proceeds from sales of marketable securities	4,403	2,597
Proceeds from maturities of marketable securities	7,927	2,338
Purchases of property, plant and equipment	(593)	(435)
Purchases of equity method investments	(154)	(3,154)
Other	(80)	(34)
Net cash provided by (used in) investing activities	963	(4,017)
Cash flows from financing activities:		
Net proceeds from issuance of debt	4,946	8,914
Repayment of debt	—	(5,000)
Repurchases of common stock	(3,532)	(2,281)
Dividends paid	(3,023)	(2,823)
Other	(104)	(87)
Net cash used in financing activities	(1,713)	(1,277)
Increase in cash and cash equivalents	5,703	3,050
Cash and cash equivalents at beginning of period	6,266	6,037
Cash and cash equivalents at end of period	$ 11,969	$ 9,087

See accompanying notes.

1. Summary of significant accounting policies

Business

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

Basis of presentation

The financial information for the three and nine months ended September 30, 2021 and 2020, 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, 2020, and with our condensed consolidated financial statements and the notes thereto contained in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2021 and June 30, 2021.

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 $9.2 billion and $9.0 billion as of September 30, 2021 and December 31, 2020, respectively.

Recent accounting pronouncements

In March 2020, the Financial Accounting Standards Board (FASB) issued a new accounting standard to ease the financial reporting burdens caused by 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 is permitted to 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. In January 2021, the FASB issued a new accounting standard to expand on the scope of the original March 2020 standard to include derivative instruments on discounting transactions. We are currently evaluating the impacts that the two standards will have on our condensed consolidated financial statements.

2. Acquisitions

On April 16, 2021, Amgen completed its acquisition of Five Prime Therapeutics, Inc. (Five Prime) for total consideration of $1.6 billion, net of cash acquired. The purchase price was funded with cash on hand. This transaction was accounted for as an asset acquisition because substantially all the value of the assets acquired was concentrated in the intellectual property rights of bemarituzumab, a phase 3 trial-ready, first-in-class program for gastric cancer. Five Prime's operations have been included in our condensed consolidated financial statements commencing after the acquisition date.

We allocated the consideration to acquire Five Prime to: the bemarituzumab in-process research and development (IPR&D) program of $1.5 billion, which was expensed immediately in Acquired IPR&D expense in the Condensed Consolidated Statements of Income; deferred tax assets of $177 million; and other net liabilities of $47 million. The acquired IPR&D expense was not tax deductible.

3. Revenues

We operate in one business segment: human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Revenues by product and by geographic area, based on customers' locations, are presented below. 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,					
	2021			2020		
	U.S.	ROW	Total	U.S.	ROW	Total
Enbrel® (etanercept)	$ 1,263	$ 26	$ 1,289	$ 1,289	$ 36	$ 1,325
Prolia® (denosumab)	530	273	803	478	223	701
Otezla® (apremilast)	495	114	609	439	99	538
XGEVA® (denosumab)	372	145	517	363	118	481
Neulasta® (pegfilgrastim)	360	55	415	484	71	555
Aranesp® (darbepoetin alfa)	149	247	396	158	226	384
Repatha® (evolocumab)	139	133	272	92	113	205
KYPROLIS® (carfilzomib)	198	95	293	173	87	260
Other products	1,052	674	1,726	1,142	513	1,655
Total product sales[1]	$ 4,558	$ 1,762	6,320	$ 4,618	$ 1,486	6,104
Other revenues			386			319
Total revenues			$ 6,706			$ 6,423

	Nine months ended September 30,					
	2021			2020		
	U.S.	ROW	Total	U.S.	ROW	Total
ENBREL	$ 3,270	$ 87	$ 3,357	$ 3,619	$ 105	$ 3,724
Prolia®	1,569	806	2,375	1,341	673	2,014
Otezla®	1,284	335	1,619	1,280	298	1,578
XGEVA®	1,061	412	1,473	1,036	361	1,397
Neulasta®	1,215	168	1,383	1,538	219	1,757
Aranesp®	409	709	1,118	489	704	1,193
Repatha®	421	423	844	331	303	634
KYPROLIS®	547	277	824	527	266	793
Other products	3,059	1,974	5,033	3,164	1,652	4,816
Total product sales[1]	$ 12,835	$ 5,191	18,026	$ 13,325	$ 4,581	17,906
Other revenues			1,107			884
Total revenues			$ 19,133			$ 18,790

[1] Hedging gains and losses, which are included in product sales, were not material for the three and nine months ended September 30, 2021 and 2020.

4. Income taxes

The effective tax rate for the three and nine months ended September 30, 2021, was 12.6% for both periods, compared with rates of 8.4% and 9.7%, respectively, for the corresponding periods of the prior year.

The increase in our effective tax rate for the three and nine months ended September 30, 2021, was primarily due to the non-deductible IPR&D expense arising from the acquisition of Five Prime and prior year favorable items partially offset by a change in earnings mix. 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 treated as a foreign jurisdiction for U.S. tax purposes, that are subject to a tax incentive grant through 2035. In addition, the Company's operations conducted in Singapore are subject to a tax incentive grant through 2034. These foreign 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 2017, we received a Revenue Agent Report (RAR) and a modified RAR from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012 proposing 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. We disagreed with the proposed adjustments and calculations and pursued a resolution with the IRS administrative appeals office. As previously reported, we were unable to reach resolution with the IRS appeals office. In July 2021, we filed a petition in the U.S. Tax Court to contest two duplicate Statutory Notices of Deficiency (Notices) for 2010, 2011 and 2012 that we received in May and July 2021. The duplicate Notices seek to increase our U.S. taxable income by an amount that would result in additional federal tax of approximately $3.6 billion, plus interest. Any additional tax that could be imposed would be reduced by up to approximately $900 million of repatriation tax previously accrued on our foreign earnings. In any event, we firmly believe that the IRS's positions in the Notices are without merit, and we will vigorously contest the Notices through the judicial process.

In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing 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, similar to those proposed for the years 2010, 2011 and 2012. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. As a consequence of the Tax Court litigation for the 2010-2012 period, the IRS administrative appeals office recently informed us that it does not plan to engage in discussions at this time regarding the allocation of profits between our entities in the United States and the U.S. territory of Puerto Rico for the 2013-2015 period. We are currently under examination by the IRS for the years 2016, 2017 and 2018. 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. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our condensed consolidated financial statements. We are no longer subject to U.S. federal income tax examinations for the years ended on or before December 31, 2009.

During the three and nine months ended September 30, 2021, the gross amounts of our unrecognized tax benefits (UTBs) increased $70 million and $180 million, respectively, as a result of tax positions taken during the current year. Substantially all of the UTBs as of September 30, 2021, if recognized, would affect our effective tax rate.

5. Earnings per share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which 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,	
	2021	2020	2021	2020
Income (Numerator):				
Net income for basic and diluted EPS	$ 1,884	$ 2,021	$ 3,994	$ 5,649
Shares (Denominator):				
Weighted-average shares for basic EPS	567	585	572	588
Effect of dilutive securities	3	4	4	4
Weighted-average shares for diluted EPS	570	589	576	592
Basic EPS	$ 3.32	$ 3.45	$ 6.98	$ 9.61
Diluted EPS	$ 3.31	$ 3.43	$ 6.93	$ 9.54

For the three and nine months ended September 30, 2021 and 2020, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

6. Collaborations

On July 30, 2021, we closed our collaboration and licensing agreement with Kyowa Kirin Co., Ltd. (KKC) to jointly develop and commercialize an anti-OX40 fully human monoclonal antibody (AMG 451) worldwide, except in Japan. AMG 451 is for the treatment of atopic dermatitis, with potential in other autoimmune diseases.

Under the terms of the agreement, we will lead the global development, manufacturing and commercialization of AMG 451, except in Japan. KKC will co-promote AMG 451 with Amgen in the United States and have opt-in rights to co-promote AMG 451 in various other markets outside the United States, including in Europe and Asia.

We made an upfront payment of $400 million to KKC that was recognized in Research and development (R&D) expense in the third quarter of 2021. Amgen and KKC will share equally the global development costs, except in Japan, and the U.S. commercialization costs. Outside of the United States and Japan, any commercialization costs incurred by KKC will be reimbursed by Amgen. We may also be required to make milestone payments of up to $850 million contingent upon the achievement of certain regulatory events and commercial thresholds. We will also pay KKC significant double-digit royalties on global sales, except in Japan.

7. 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, 2021	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 51	$ —	$ —	$ 51
U.S. Treasury bills	3,900	—	—	3,900
Money market mutual funds	8,323	—	—	8,323
Other short-term interest-bearing securities	1	—	—	1
Total interest-bearing securities	$ 12,275	$ —	$ —	$ 12,275

Types of securities as of December 31, 2020	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 129	$ 1	$ —	$ 130
U.S. Treasury bills	4,948	—	—	4,948
Money market mutual funds	4,765	—	—	4,765
Other short-term interest-bearing securities	2	—	—	2
Total interest-bearing securities	$ 9,844	$ 1	$ —	$ 9,845

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, 2021	December 31, 2020
Cash and cash equivalents	$ 11,323	$ 5,464
Marketable securities	952	4,381
Total interest-bearing securities	$ 12,275	$ 9,845

Cash and cash equivalents in the above table excludes bank account cash of $646 million and $802 million as of September 30, 2021 and December 31, 2020, respectively.

The fair values of available-for-sale investments by contractual maturity were as follows (in millions):

Contractual maturities	September 30, 2021	December 31, 2020
Maturing in one year or less	$ 12,275	$ 9,795
Maturing after one year through three years	—	50
Total available-for-sale investments	$ 12,275	$ 9,845

For the three and nine months ended September 30, 2021 and 2020, realized gains and losses on interest-bearing securities were not material. Realized gains and losses on interest-bearing securities are recorded in 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 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 $608 million and $477 million as of September 30, 2021 and December 31, 2020, respectively, which are included in Other noncurrent assets in the Condensed Consolidated Balance Sheets. For the three months ended September 30, 2021 and 2020, net unrealized gains on publicly traded securities were $135 million and $60 million, respectively. For the nine months ended September 30, 2021 and 2020, net unrealized gains on publicly traded securities were $104 million and $65 million, respectively. Realized gains and losses on sales of publicly traded securities for the three and nine months ended September 30, 2021 and 2020 were not material.

We held investments of $255 million and $203 million in equity securities without readily determinable fair values as of September 30, 2021 and December 31, 2020, respectively, which are included in Other noncurrent assets in the Condensed Consolidated Balance Sheets. For the three months ended September 30, 2021 and 2020, gains due to upward adjustments on these securities were $94 million and $12 million, respectively. For the nine months ended September 30, 2021 and 2020, gains due to upward adjustments on these securities were $129 million and $20 million, respectively. Downward adjustments on these securities were not material. Adjustments were based on observable price transactions.

Equity method investments

BeiGene, Ltd.

As of September 30, 2021, we had an ownership interest of approximately 20.3% in BeiGene, Ltd. (BeiGene), which is included in Other noncurrent assets in the Condensed Consolidated Balance Sheets and accounted for under the equity method of accounting. We amortize the difference between the fair value of equity securities acquired and our proportionate share of the carrying value of the underlying net assets of BeiGene over the useful lives of the assets that gave rise to this basis difference. This amortization and our share of the results of operations of BeiGene are included in Other income, net, in the Condensed Consolidated Statements of Income one quarter in arrears, which began in the second quarter of 2020.

During the three and nine months ended September 30, 2021, the carrying value of our equity investment was adjusted by our share of BeiGene's net loss of $98 million and $181 million, respectively, and amortization of the basis difference of $44 million and $128 million, respectively. During the three and nine months ended September 30, 2021, the carrying value increased by $18 million and $56 million, respectively, from the impact of BeiGene ownership transactions. In addition, during the three and nine months ended September 30, 2021, we increased the carrying value by $50 million as a result of our purchase of additional shares directly from BeiGene. As of September 30, 2021, the carrying value and fair value of our investment in BeiGene totaled $2.7 billion and $6.9 billion, respectively. As of September 30, 2021, we believe the carrying value of our equity investment in BeiGene is fully recoverable.

Neumora Therapeutics, Inc.

On September 30, 2021, we acquired approximately 25.9% ownership interest in Neumora Therapeutics, Inc. (Neumora), a privately held company, for $257 million, which is included in Other noncurrent assets in the Condensed Consolidated Balance Sheets, in exchange for a $100 million cash payment and $157 million in noncash consideration primarily related to future services. Although our equity investment provides us with the ability to exercise significant influence over Neumora, we have elected the fair value option to account for our equity investment. Under the fair value option, changes in the fair value of the investment are recognized through earnings each reporting period. We believe the fair value option best reflects the economics of the underlying transaction.

Limited partnerships

We held limited partnership investments of $556 million and $496 million as of September 30, 2021 and December 31, 2020, respectively, which are included in Other noncurrent 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, 2021, unfunded additional commitments to be made for these investments during the next several years were not material. For the three months ended September 30, 2021 and 2020, net unrealized gains and losses on our limited partnership investments were a net loss of $43 million and a net gain of $63 million, respectively. For the nine months ended September 30, 2021 and 2020, net unrealized gains from our limited partnership investments were $122 million and $73 million, respectively.

8. Inventories

Inventories consisted of the following (in millions):

	September 30, 2021	December 31, 2020
Raw materials	$ 667	$ 486
Work in process	2,313	2,437
Finished goods	1,172	970
Total inventories	$ 4,152	$ 3,893

9. Goodwill and other intangible assets

Goodwill

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

	Nine months ended September 30, 2021
Beginning balance	$ 14,689
Currency translation adjustment	(24)
Ending balance	$ 14,665

Other intangible assets

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

	September 30, 2021			December 31, 2020		
	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	$ 25,575	$ (12,222)	$ 13,353	$ 25,591	$ (10,564)	$ 15,027
Licensing rights	3,766	(2,931)	835	3,743	(2,791)	952
Marketing-related rights	1,362	(1,099)	263	1,367	(1,041)	326
Research and development technology rights	1,298	(1,120)	178	1,317	(1,065)	252
Total finite-lived intangible assets	32,001	(17,372)	14,629	32,018	(15,461)	16,557
Indefinite-lived intangible assets:						
In-process research and development	30	—	30	30	—	30
Total other intangible assets	$ 32,031	$ (17,372)	$ 14,659	$ 32,048	$ (15,461)	$ 16,587

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 upfront 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.

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, 2021 and 2020, we recognized amortization associated with our finite-lived intangible assets of $642 million and $708 million, respectively. During the nine months ended September 30, 2021 and 2020, we recognized amortization associated with our finite-lived intangible assets of $1.9 billion and $2.1 billion, 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, 2021, and the years ending December 31, 2022, 2023, 2024, 2025 and 2026, are $0.6 billion, $2.5 billion, $2.4 billion, $2.4 billion, $2.2 billion and $1.8 billion, respectively.

10. Financing arrangements

Our borrowings consisted of the following (in millions):

	September 30, 2021	December 31, 2020
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	$ 1,448	$ 1,527
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)	751	791
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	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)	869	916
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)	640	649
2.20% notes due 2027 (2.20% 2027 Notes)	1,750	1,750
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
1.65% note due 2028 (1.65% 2028 Notes)	1,250	—
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	943	957
2.45% notes due 2030 (2.45% 2030 Notes)	1,250	1,250
2.30% notes due 2031 (2.30% 2031 Notes)	1,250	1,250
2.00% notes due 2032 (2.00% 2032 Notes)	1,250	—
6.375% notes due 2037 (6.375% 2037 Notes)	478	478
6.90% notes due 2038 (6.90% 2038 Notes)	254	254
6.40% notes due 2039 (6.40% 2039 Notes)	333	333
3.15% notes due 2040 (3.15% 2040 Notes)	2,000	2,000
5.75% notes due 2040 (5.75% 2040 Notes)	373	373
2.80% note due 2041 (2.80% 2041 Notes)	1,150	—
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	729	729
5.65% notes due 2042 (5.65% 2042 Notes)	415	415
5.375% notes due 2043 (5.375% 2043 Notes)	185	185
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	2,250
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
3.00% notes due 2052 (3.00% 2052 Notes)	1,350	—
2.77% notes due 2053 (2.77% 2053 Notes)	940	940
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(1,221)	(1,188)
Fair value adjustments	371	566
Other	15	5
Total carrying value of debt	37,579	32,986
Less current portion	(4,288)	(91)
Total long-term debt	$ 33,291	$ 32,895

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.

During the three months ended September 30, 2021, we issued $5.0 billion of debt consisting of $1.25 billion of the 1.65% 2028 Notes, $1.25 billion of the 2.00% 2032 Notes, $1.15 billion of the 2.80% 2041 Notes and $1.35 billion of the 3.00% 2052 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 a specified period of time immediately prior to the maturing of the notes. Such time periods range from two months to six months prior to maturity.

During the three months ended June 30, 2021, we entered into the following interest rate swap contracts: (i) $1.0 billion notional amount with respect to the 2.45% 2030 Notes, resulting in an effective interest rate of three-month LIBOR plus 1.0% for that portion of the notes, and (ii) $500 million notional amount with respect to the 2.30% 2031 Notes, resulting in an effective interest rate of three-month LIBOR plus 0.8% for that portion of the notes.

11. Stockholders' equity

Stock repurchase program

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

	2021		2020	
	Shares	Dollars	Shares	Dollars
First quarter	3.7	$ 865	4.3	$ 933
Second quarter	6.5	1,592	2.6	591
Third quarter	4.6	1,069	3.0	752
Total stock repurchases	14.8	$ 3,526	9.9	$ 2,276

In March 2021, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $3.4 billion. As of September 30, 2021, $2.9 billion of authorization remained available under our stock repurchase program.

In October 2021, the Board of Directors increased the amount authorized under our stock repurchase program by an additional $4.5 billion.

Dividends

In July 2021, March 2021 and December 2020, the Board of Directors declared a quarterly cash dividend of $1.76 per share, which were paid in September 2021, June 2021 and March 2021, respectively. In October 2021, the Board of Directors declared a quarterly cash dividend of $1.76 per share, which will be paid on December 8, 2021.

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, 2020	$ (709)	$ (263)	$ 1	$ (14)	$ (985)
Foreign currency translation adjustments	(39)	—	—	—	(39)
Unrealized gains	—	108	—	—	108
Reclassification adjustments to income	—	133	—	—	133
Other	—	—	—	1	1
Income taxes	—	(51)	—	—	(51)
Balance as of March 31, 2021	(748)	(73)	1	(13)	(833)
Foreign currency translation adjustments	14	—	—	—	14
Unrealized losses	—	(31)	—	—	(31)
Reclassification adjustments to income	—	(28)	—	—	(28)
Other	—	—	—	(1)	(1)
Income taxes	—	11	—	—	11
Balance as of June 30, 2021	(734)	(121)	1	(14)	(868)
Foreign currency translation adjustments	(35)	—	—	—	(35)
Unrealized gains (losses)	—	16	(1)	—	15
Reclassification adjustments to income	—	109	—	—	109
Other	—	—	—	(3)	(3)
Income taxes	—	(26)	—	—	(26)
Balance as of September 30, 2021	$ (769)	$ (22)	$ —	$ (17)	$ (808)

Reclassifications out of AOCI and into earnings, including related income tax expenses, were as follows (in millions):

Components of AOCI	Three months ended September 30, 2021	2020	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract (losses) gains	$ (5)	$ 41	Product sales
Cross-currency swap contract (losses) gains	(104)	183	Other income, net
	(109)	224	Income before income taxes
	23	(49)	Provision for income taxes
	$ (86)	$ 175	Net income
Available-for-sale securities:			
Net realized gains	$ —	$ —	Other income, net
	—	—	Provision for income taxes
	$ —	$ —	Net income

Components of AOCI	Nine months ended September 30, 2021	2020	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract (losses) gains	$ (24)	$ 158	Product sales
Cross-currency swap contract (losses) gains	(190)	101	Other income, net
	(214)	259	Income before income taxes
	45	(57)	Provision for income taxes
	$ (169)	$ 202	Net income
Available-for-sale securities:			
Net realized gains	$ —	$ 33	Other income, net
	—	(7)	Provision for income taxes
	$ —	$ 26	Net income

12. Fair value measurement

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

Level 1	—	Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability t 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 different 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, 2021, 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	$ 51	$ —	$ —	$ 51
U.S. Treasury bills	3,900	—	—	3,900
Money market mutual funds	8,323	—	—	8,323
Other short-term interest-bearing securities	—	1	—	1
Equity securities	608	—	257	865
Derivatives:				
Foreign currency contracts	—	127	—	127
Cross-currency swap contracts	—	119	—	119
Interest rate swap contracts	—	29	—	29
Total assets	$ 12,882	$ 276	$ 257	$ 13,415
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 54	$ —	$ 54
Cross-currency swap contracts	—	360	—	360
Interest rate swap contracts	—	105	—	105
Contingent consideration obligations	—	—	35	35
Total liabilities	$ —	$ 519	$ 35	$ 554

Fair value measurement as of December 31, 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	$ 130	$ —	$ —	$ 130
U.S. Treasury bills	4,948	—	—	4,948
Money market mutual funds	4,765	—	—	4,765
Other short-term interest-bearing securities	—	2	—	2
Equity securities	477	—	—	477
Derivatives:				
Foreign currency contracts	—	28	—	28
Cross-currency swap contracts	—	255	—	255
Interest rate swap contracts	—	66	—	66
Total assets	$ 10,320	$ 351	$ —	$ 10,671
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 237	$ —	$ 237
Cross-currency swap contracts	—	318	—	318
Interest rate swap contracts	—	15	—	15
Contingent consideration obligations	—	—	33	33
Total liabilities	$ —	$ 570	$ 33	$ 603

Interest-bearing and equity securities

The fair values of our U.S. Treasury securities, money market mutual funds and equity investments in publicly traded securities are based on quoted market prices in active markets, with no valuation adjustment. The fair value of equity securities without readily determinable fair values are initially valued at the transaction price and subsequently valued based upon a combination of entity-specific financial information and publicly available market information for similar companies that have actively traded equity securities.

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 13, Derivative instruments.

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

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

During the three and nine months ended September 30, 2021 and 2020, 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, 2021 and December 31, 2020, the aggregate fair values of our borrowings were $42.2 billion and $39.4 billion, respectively, and the carrying values were $37.6 billion and $33.0 billion, respectively.

13. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we use or have used certain derivative instruments, including foreign currency forward, 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 up to a maximum of three years into the future; and at any given point in time, a higher percentage of nearer-term projected product sales are being hedged than in successive periods.

As of September 30, 2021 and December 31, 2020, we had outstanding foreign currency forward contracts with aggregate notional amounts of $5.7 billion and $5.1 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 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, 2021, were as follows (notional amounts in millions):

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

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, 2021, and amounts expected to be recognized during the subsequent 12 months are not material.

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

	Three months ended September 30,		Nine months ended September 30,	
Derivatives in cash flow hedging relationships	**2021**	**2020**	**2021**	**2020**
Foreign currency contracts	$ 136	$ (163)	$ 273	$ (25)
Cross-currency swap contracts	(120)	223	(180)	(107)
Total unrealized gains (losses)	$ 16	$ 60	$ 93	$ (132)

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, 2021 and December 31, 2020, we had interest rate swap contracts with aggregate notional amounts of $7.4 billion and $5.9 billion, respectively, that hedge certain portions of our long-term debt issuances. During the three months ended June 30, 2021, we entered into $1.5 billion of interest rate swap contracts to hedge portions of our 2.45% 2030 Notes and 2.30% 2031 Notes (see Note 10, Financing arrangements).

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

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

	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
Condensed Consolidated Balance Sheets locations	**September 30, 2021**	**December 31, 2020**	**September 30, 2021**	**December 31, 2020**
Current portion of long-term debt	$ 840	$ 89	$ 90	$ 89
Long-term debt	$ 6,809	$ 6,258	$ 281	$ 477

(1) Current portion of long-term debt includes $87 million and $89 million of carrying value with discontinued hedging relationships as of September 30, 2021 and December 31, 2020, respectively. Long-term debt includes $460 million and $525 million of carrying value with discontinued hedging relationships as of September 30, 2021 and December 31, 2020, respectively.

(2) Current portion of long-term debt includes $87 million and $89 million of hedging adjustments on discontinued hedging relationships as of September 30, 2021 and December 31, 2020, respectively. Long-term debt includes $360 million and $425 million of hedging adjustments on discontinued hedging relationships as of September 30, 2021 and December 31, 2020, 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, 2021			Nine months ended September 30, 2021		
	Product sales	Other income, net	Interest expense, net	Product sales	Other income, net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Condensed Consolidated Statements of Income	$ 6,320	$ 73	$ (296)	$ 18,026	$ 97	$ (862)
The effects of cash flow and fair value hedging:						
Losses on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency contracts	$ (5)	$ —	$ —	$ (24)	$ —	$ —
Cross-currency swap contracts	$ —	$ (104)	$ —	$ —	$ (190)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:						
Hedged items[1]	$ —	$ —	$ 54	$ —	$ —	$ 195
Derivatives designated as hedging instruments	$ —	$ —	$ (31)	$ —	$ —	$ (128)

	Three months ended September 30, 2020			Nine months ended September 30, 2020		
	Product sales	Other income, net	Interest expense, net	Product sales	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)

[1] Gains on hedged items do not exactly offset 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 when 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, 2021, the net gains expected to be reclassified on our foreign currency and cross-currency swap contracts out of AOCI and into earnings during the next 12 months are not material.

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, 2021 and December 31, 2020, the total notional amounts of these foreign currency forward contracts were $0.7 billion and $1.0 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, 2021 and 2020.

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

	Derivative assets		Derivative liabilities	
September 30, 2021	**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 noncurrent assets	$ 127	Accrued liabilities/ Other noncurrent liabilities	$ 54
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	119	Accrued liabilities/ Other noncurrent liabilities	360
Interest rate swap contracts	Other current assets/ Other noncurrent assets	29	Accrued liabilities/ Other noncurrent liabilities	105
Total derivatives designated as hedging instruments		$ 275		$ 519

	Derivative assets		Derivative liabilities	
December 31, 2020	**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 noncurrent assets	$ 28	Accrued liabilities/ Other noncurrent liabilities	$ 237
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	255	Accrued liabilities/ Other noncurrent liabilities	318
Interest rate swap contracts	Other current assets/ Other noncurrent assets	66	Accrued liabilities/ Other noncurrent liabilities	15
Total derivatives designated as hedging instruments		$ 349		$ 570

Our derivative contracts that were in liability positions as of September 30, 2021, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the contracts may be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

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

14. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See our Annual Report on Form 10-K for the year ended December 31, 2020, 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, 2020; in Note 12, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2021; and in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended June 30, 2021.

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, 2020; in Note 12, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2021; or in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended June 30, 2021, 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, 2020; in Note 12, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2021; or in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended June 30, 2021, 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 September 28, 2021, consistent with its September 20, 2021 opinion and order, the U.S. District Court for the District of New Jersey (the New Jersey District Court) entered final judgment in favor of Amgen and against Zydus Pharmaceuticals (USA) Inc. (Zydus) with respect to claims 3 and 6 of U.S. Patent No. 7,427,638 (the ’638 Patent), claim 6 of U.S. Patent No. 8,455,536 (the ’536 Patent) and claims 2 and 27 of U.S. Patent No. 8,093,283 (the ‘283 Patent); and final judgment in favor of Zydus and against Amgen with respect to claims 1 and 15 of U.S. Patent No. 7,893,101 (the ‘101 Patent) and claims 2, 19 and 21 of U.S. Patent No. 10,092,541 (the ’541 Patent). The final judgment ordered that the effective date of any final approval by the U.S. Food and Drug Administration (FDA) of Zydus’s ANDA must be after expiration of the three infringed patents (the ’638, ’536 and ’283 Patents) and any regulatory exclusivity to which Amgen may become entitled. The final judgment also includes an injunction prohibiting Zydus from making, using, offering to sell, or selling in the United States, or importing into the United States, Zydus’s generic apremilast products during the term of the three infringed patents.

On October 12, 2021, the New Jersey District Court also entered final judgment in favor of Amgen and against Sandoz Inc. (Sandoz) with respect to claims 3 and 6 of the ’638 Patent, claim 6 of the ’536 Patent and claims 1 and 15 of the ’101 Patent; and final judgment in favor of Sandoz and against Amgen with respect to claims 2, 19 and 21 of the ’541 Patent. The final judgment ordered that the effective date of any final approval by the FDA of Sandoz’s ANDA must be after expiration of the three infringed patents (the ’638, ’536 and ’101 Patents) and any regulatory exclusivity to which Amgen may become entitled. The final judgment also includes an injunction prohibiting Sandoz from making, using, offering to sell, or selling in the United States, or importing into the United States, Sandoz’s generic apremilast products during the term of the three infringed patents.

Zydus and Amgen filed notices of appeal to the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court) on October 27, 2021 and October 28, 2021, respectively.

Sensipar® (cinacalcet) ANDA Patent Litigation

Amgen Inc. v. Amneal Pharmaceuticals LLC, et al. (formerly, Amgen Inc. v. Aurobindo Pharma Ltd. et al.)

On October 20, 2021, the U.S. District Court for the District of Delaware (the Delaware District Court) issued final judgment in favor of Piramal Healthcare UK Limited and Slate Run Pharmaceuticals LLC.

ENBREL Patent Litigation

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

On November 2, 2021, Amgen and Samsung Bioepis Co., Ltd. (Bioepis), with the consent of Hoffmann-La Roche Inc. (Roche), jointly submitted to the New Jersey District Court a confidential stipulation and a form of final judgment and order of permanent injunction resolving the dispute between the parties and enjoining Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, any product containing etanercept until the April 24, 2029 expiry of Roche’s U.S. Patent No. 8,163,522.

Repatha® Patent Litigation

Patent Disputes in the International Region

National litigations in the United Kingdom, France, the Netherlands and Italy have been settled. In Germany, Sanofi-Aventis Deutschland GmbH and Regeneron Pharmaceuticals, Inc. have filed actions claiming they are entitled to damages arising from the provisional enforcement of an injunction against PRALUENT® that was lifted after the European Patent Office Technical Board of Appeal’s October 29, 2020 ruling that certain claims encompassing PRALUENT® in Amgen’s European Patent No. 2,215,124 were invalid.

NEUPOGEN® (filgrastim)/Neulasta® Patent Litigation

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

On September 8, 2021, pursuant to joint stipulation, the Delaware District Court dismissed the lawsuits regarding U.S. Patent Nos. 9,643,997 and 10,577,392.

Patent Trial and Appeal Board (PTAB) Challenge

Apotex PTAB Challenge

On September 2, 2021, the Federal Circuit Court issued a remand to permit Amgen to request rehearing of the PTAB’s final written decision holding that all claims of U.S. Patent No. 8.952,138 as unpatentable.

Pfizer PTAB Challenge

On February 10, 2021, Hospira, Inc. and Pfizer Inc. (collectively, Pfizer) filed a petition to institute inter partes review (IPR) proceeding at the U.S. Patent and Trademark Office (USPTO) of U.S. Patent No. 8,273,707 (the ’707 Patent), challenging claims of the ’707 Patent as unpatentable. Amgen’s preliminary response was filed on May 18, 2021.

On August 17, 2021, the PTAB of the USPTO granted Pfizer’s petition to institute IPR of the ’707 Patent. On August 23, 2021, the PTAB issued the schedule for the proceeding, including oral argument (if requested) on May 18, 2022.

Breach of Contract Action

Novartis Pharma AG v. Amgen Inc.

On October 26, 2021, the U.S. District Court for the Southern District of New York held a status conference with the parties and set the dates for Novartis Pharma AG's (Novartis) opening brief for its motion for partial summary judgment on two claims, fraudulent inducement and negligent misrepresentation, to be due on January 14, 2022, Amgen's opposition to be due on February 14, 2022 and Novartis' reply to be due on March 10, 2022. This motion, if granted, will not dispose of the entire case as other claims related to breach of contract remain pending.

U.S. Tax Litigation

Amgen Inc. & Subsidiaries v. Commissioner of Internal Revenue

See Note 4, Income taxes, for discussion of the IRS tax dispute and the Company's petition in the U.S. Tax Court.

15. Subsequent event

On October 19, 2021, Amgen completed its acquisition of Teneobio, Inc. (Teneobio), a privately held, clinical-stage biotechnology company developing a new class of biologics called heavy-chain only antibodies (HCAbs). Amgen acquired all outstanding shares in exchange for a $900 million upfront payment, as well as future contingent milestone payments potentially worth up to an additional $1.6 billion in cash upon the achievement of certain development and regulatory events.

The accounting impact of this acquisition and the results of operations for Teneobio will be included in our consolidated financial statements beginning in the fourth quarter of 2021. The initial accounting for this acquisition is incomplete, pending identification and measurement of the assets acquired and liabilities assumed.

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, 2020, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2021 and June 30, 2021. 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, 2020, and in Part II, Item 1A. Risk Factors of our Quarterly Reports on Form 10-Q for the periods ended March 31, 2021 and June 30, 2021. 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.

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

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 on March 11, 2020. Since the onset of the pandemic in 2020, we have been closely monitoring the pandemic's effects on our global operations. We continue to take appropriate steps to minimize risks to our employees, a significant number of whom have continued to work virtually. Employee access to company facilities has been 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 to or shortages of our supply of medicines.

Since the beginning of the COVID-19 pandemic, we have seen changes in demand for some of our products driven by changes in patient visits to doctors' offices that has impacted providing treatments to existing patients and reduced diagnoses in new patients. Through the third quarter, there has been gradual recovery in both patient visits and diagnoses, although overall these remain below pre-COVID-19 levels. The cumulative decrease in diagnoses over the course of the pandemic has suppressed the volume of new patients starting treatment, which we expect to continue to impact our business during the remainder of the year. We are closely monitoring the effects of emerging COVID-19 variants on patient behavior and access.

Since early 2021, global vaccination efforts have been underway to control the pandemic. However, uncertainty remains as to the length of time required for vaccination of a meaningful portion of the population and as to the efficacy of such vaccinations on the trajectory of the pandemic. Challenges to vaccination efforts, new variants and other causes of virus spread may require governments to issue additional restrictions and/or shutdowns in various geographies. As a result, we expect to see continued volatility for at least the duration of the pandemic as governments respond to current local conditions.

With respect to our drug development activities, we are continuously monitoring COVID-19 infection rates, including changes from new variants, and working to mitigate effects on future study enrollment in our clinical trials and evaluating the impact in all countries where clinical trials occur. We remain focused on supporting our active clinical sites in their providing care for patients and in our providing investigational drug supply.

Despite the ongoing pandemic and business impacts noted above, 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 expenditures and debt service requirements as well as to engage in the capital-return and other business initiatives that we plan to pursue. For a discussion of the risks the COVID-19 pandemic presents to our results, see Risk Factors 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, 2020, and in Part II, Item 1A. Risk Factors of our Quarterly Reports on Form 10-Q for the periods ended March 31, 2021 and June 30, 2021.

Significant developments

Following is a summary of selected significant developments affecting our business that occurred since the filing of our Quarterly Report on Form 10-Q for the period ended June 30, 2021. 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, 2020, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2021 and June 30, 2021.

Business Development

Acquisition

Teneobio

- On October 19, 2021, Amgen completed its acquisition of Teneobio, a privately held, clinical-stage biotechnology company, for $900 million as well as future contingent milestone payments potentially worth up to an additional $1.6 billion upon the achievement of certain development and regulatory events.

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,		
	2021	2020	Change	2021	2020	Change
Product sales						
U.S.	$ 4,558	$ 4,618	(1) %	$ 12,835	$ 13,325	(4) %
ROW	1,762	1,486	19 %	5,191	4,581	13 %
Total product sales	6,320	6,104	4 %	18,026	17,906	1 %
Other revenues	386	319	21 %	1,107	884	25 %
Total revenues	$ 6,706	$ 6,423	4 %	$ 19,133	$ 18,790	2 %
Operating expenses	$ 4,328	$ 3,970	9 %	$ 13,798	$ 11,659	18 %
Operating income	$ 2,378	$ 2,453	(3) %	$ 5,335	$ 7,131	(25) %
Net income	$ 1,884	$ 2,021	(7) %	$ 3,994	$ 5,649	(29) %
Diluted EPS	$ 3.31	$ 3.43	(3) %	$ 6.93	$ 9.54	(27) %
Diluted shares	570	589	(3) %	576	592	(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 months ended September 30, 2021, primarily driven by higher unit demand for certain brands, including Prolia®, Repatha® and EVENITY®, and by favorable changes to estimated sales deductions, partially offset by declines in the net selling prices of certain products. Total product sales increased for the nine months ended September 30, 2021, primarily driven by higher unit demand for certain brands, including Prolia®, Repatha® and MVASI®, partially offset by declines in the net selling prices of certain products. We expect the trend of net selling price declines to continue to affect our business. Going forward, we expect that net selling price declines will be driven by ENBREL, Neulasta®, Repatha®and some of our biosimilar products. There was gradual recovery through the third quarter of 2021 in patients resuming their treatments and in new patient starts, although overall, both numbers remain below pre-COVID-19 levels.

Throughout the pandemic, we experienced changes in demand for some of our products. The pandemic has interrupted many physician–patient interactions, which has led to delays in diagnoses and treatments, with varying degrees of impact across our portfolio. In general, declines in the sales of our products that were impacted by the dynamics of the pandemic were most significant in the early months of the pandemic with product demand beginning to show some recovery in late 2020. Through the third quarter of 2021, demand continued to gradually recover from the impact of the pandemic and there was improvement in patient visits and diagnoses. Healthcare provider activity also stabilized during the third quarter after having improved during the first half of 2021. However, the cumulative decrease in diagnoses over the course of the pandemic has suppressed the volume of new patients starting treatment, which we expect to continue to impact our business for the remainder of the year. Given the unpredictable nature of the pandemic, we expect there could be ongoing intermittent disruptions in physician–patient interactions, and as a result, we continue to expect quarter-to-quarter variability. In addition, other changes in the healthcare ecosystem have the potential to introduce variability into product sales trends. For example, we expect changes in U.S. employment to lead to changes to the insured population. Growth in numbers of Medicaid enrollees and uninsured individuals may have a negative impact on product demand and sales. Overall, uncertainty remains around the timing and magnitude of our sales during the COVID-19 pandemic. See Risk Factors in Part II, Item 1A. of this Form 10-Q and Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2020, and in Part II, Item 1A. Risk Factors of our Quarterly Reports on Form 10-Q for the periods ended March 31, 2021 and June 30, 2021.

Other revenues increased for the three and nine months ended September 30, 2021, primarily driven by the sale of COVID-19 antibody material.

Operating expenses increased for the three months ended September 30, 2021, primarily driven by an upfront payment associated with the KKC licensing agreement. Operating expenses increased for the nine months ended September 30, 2021, primarily driven by IPR&D expense related to the bemarituzumab program acquired as part of the Five Prime acquisition and by an upfront payment associated with the KKC licensing agreement.

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, 2021 and 2020.

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,		
	2021	2020	Change	2021	2020	Change
ENBREL	$ 1,289	$ 1,325	(3) %	$ 3,357	$ 3,724	(10) %
Prolia®	803	701	15 %	2,375	2,014	18 %
Otezla®	609	538	13 %	1,619	1,578	3 %
XGEVA®	517	481	7 %	1,473	1,397	5 %
Neulasta®	415	555	(25) %	1,383	1,757	(21) %
Aranesp®	396	384	3 %	1,118	1,193	(6) %
Repatha®	272	205	33 %	844	634	33 %
KYPROLIS®	293	260	13 %	824	793	4 %
Other products	1,726	1,655	4 %	5,033	4,816	5 %
Total product sales	$ 6,320	$ 6,104	4 %	$ 18,026	$ 17,906	1 %

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, 2020: (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, 2021 and June 30, 2021, 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,		
	2021	2020	Change	2021	2020	Change
ENBREL — U.S.	$ 1,263	$ 1,289	(2) %	$ 3,270	$ 3,619	(10) %
ENBREL — Canada	26	36	(28) %	87	105	(17) %
Total ENBREL	$ 1,289	$ 1,325	(3) %	$ 3,357	$ 3,724	(10) %

The decrease in ENBREL sales for the three months ended September 30, 2021, was driven by a decline in unit demand, unfavorable changes in inventory and lower net selling price, partially offset by favorable changes to estimated sales deductions. The decrease in ENBREL for the nine months ended September 30, 2021, was driven by declines in net selling price and unit demand. For the remainder of 2021, we expect the trend of net selling price declines to continue compared with the prior year.

We are involved in patent litigation with a company seeking to market its FDA-approved biosimilar version 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, 2020, and Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended June 30, 2021. 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. Other companies are also developing proposed biosimilar versions of ENBREL.

Prolia®

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

	Three months ended September 30,			Nine months ended September 30,		
	2021	2020	Change	2021	2020	Change
Prolia® — U.S.	$ 530	$ 478	11 %	$ 1,569	$ 1,341	17 %
Prolia® — ROW	273	223	22 %	806	673	20 %
Total Prolia®	$ 803	$ 701	15 %	$ 2,375	$ 2,014	18 %

The increase in global Prolia® sales for the three and nine months ended September 30, 2021, was primarily driven by higher unit demand.

Otezla®

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

	Three months ended September 30,			Nine months ended September 30,		
	2021	2020	Change	2021	2020	Change
Otezla® — U.S.	$ 495	$ 439	13 %	$ 1,284	$ 1,280	— %
Otezla® — ROW	114	99	15 %	335	298	12 %
Total Otezla®	$ 609	$ 538	13 %	$ 1,619	$ 1,578	3 %

The increase in global Otezla® sales for the three months ended September 30, 2021, was primarily driven by higher unit demand and favorable changes to estimated sales deductions, partially offset by lower net selling price. The increase in global Otezla® sales for the nine months ended September 30, 2021, was driven by higher unit demand, partially offset by lower net selling price.

For a discussion of litigation related to Otezla®, 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, 2020; Notes 12 and 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2021 and June 30, 2021, respectively; and Note 14, Contingencies and commitments, to the condensed consolidated financial statements in this Quarterly Report.

XGEVA®

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

	Three months ended September 30,			Nine months ended September 30,		
	2021	2020	Change	2021	2020	Change
XGEVA® — U.S.	$ 372	$ 363	2 %	$ 1,061	$ 1,036	2 %
XGEVA® — ROW	145	118	23 %	412	361	14 %
Total XGEVA®	$ 517	$ 481	7 %	$ 1,473	$ 1,397	5 %

The increase in global XGEVA® sales for the three and nine months ended September 30, 2021, was driven by higher unit demand, partially offset by lower net selling price.

Neulasta®

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

	Three months ended September 30,			Nine months ended September 30,		
	2021	2020	Change	2021	2020	Change
Neulasta® — U.S.	$ 360	$ 484	(26) %	$ 1,215	$ 1,538	(21) %
Neulasta® — ROW	55	71	(23) %	168	219	(23) %
Total Neulasta®	$ 415	$ 555	(25) %	$ 1,383	$ 1,757	(21) %

The decrease in global Neulasta® sales for the three months ended September 30, 2021, was primarily driven by the impact of biosimilar competition on net selling price and unit demand. The decrease in global Neulasta® sales for the nine months ended September 30, 2021, was driven by the impact of biosimilar competition on net selling price and unit demand, partially offset by favorable changes to estimated sales deductions. Increased competition in the United States and Europe as a result of biosimilar versions of Neulasta® has had and will continue to have a significant adverse impact on brand sales, including additional net price erosion and lower unit demand. We also expect other biosimilar versions to be approved in the future.

For a discussion of ongoing patent litigations related to 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, 2020; Notes 12 and 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2021 and June 30, 2021, respectively; and Note 14, Contingencies and commitments, to the condensed consolidated financial statements in this Quarterly Report.

Aranesp®

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

	Three months ended September 30,			Nine months ended September 30,		
	2021	2020	Change	2021	2020	Change
Aranesp® — U.S.	$ 149	$ 158	(6) %	$ 409	$ 489	(16) %
Aranesp® — ROW	247	226	9 %	709	704	1 %
Total Aranesp®	$ 396	$ 384	3 %	$ 1,118	$ 1,193	(6) %

The increase in global Aranesp® sales for the three months ended September 30, 2021, was driven by higher unit demand and favorable changes to estimated sales deductions, partially offset by lower net selling price due to competition. The decrease in global Aranesp® sales for the nine months ended September 30, 2021, was primarily driven by lower net selling price due to competition.

Aranesp® continues to face competition from a long-acting erythropoiesis-stimulating agent (ESA) and also faces competition from a biosimilar version of EPOGEN®, which will continue to impact sales in the future.

Repatha®

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

	Three months ended September 30,			Nine months ended September 30,		
	2021	2020	Change	2021	2020	Change
Repatha® — U.S.	$ 139	$ 92	51 %	$ 421	$ 331	27 %
Repatha® — ROW	133	113	18 %	423	303	40 %
Total Repatha®	$ 272	$ 205	33 %	$ 844	$ 634	33 %

The increase in global Repatha® sales for the three and nine months ended September 30, 2021, was primarily driven by higher unit demand, partially offset by lower net selling price.

For a discussion of ongoing litigation related to Repatha®, 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, 2020; Notes 12 and 13, Contingencies and commitments, to the condensed consolidated financial statements for the periods ended March 31, 2021 and June 30, 2021, respectively; and Note 14, Contingencies and commitments, to the condensed consolidated financial statements in this Quarterly Report.

KYPROLIS®

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

	Three months ended September 30,			Nine months ended September 30,		
	2021	2020	Change	2021	2020	Change
KYPROLIS® — U.S.	$ 198	$ 173	14 %	$ 547	$ 527	4 %
KYPROLIS® — ROW	95	87	9 %	277	266	4 %
Total KYPROLIS®	$ 293	$ 260	13 %	$ 824	$ 793	4 %

The increase in global KYPROLIS® sales for the three and nine months ended September 30, 2021, was primarily driven by higher unit demand.

We are engaged in litigation with two companies that are challenging certain of our 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, 2020; and Notes 12 and 13, Contingencies and commitments, to the condensed consolidated financial statements for the periods ended March 31, 2021 and June 30, 2021, respectively. The FDA has reported that it has granted tentative or final approval of ANDAs for generic carfilzomib products filed by a number of companies. The date of approval of those ANDAs for generic carfilzomib products is governed by the Hatch-Waxman Act and any applicable settlement agreements between the parties.

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,		
	2021	2020	Change	2021	2020	Change
MVASI® — U.S.	$ 187	$ 185	1 %	$ 617	$ 442	40 %
MVASI® — ROW	87	46	89 %	245	76	*
Nplate® — U.S.	156	118	32 %	404	352	15 %
Nplate® — ROW	117	94	24 %	341	271	26 %
Vectibix® — U.S.	84	90	(7)%	255	249	2 %
Vectibix® — ROW	116	103	13 %	375	341	10 %
KANJINTI® — U.S.	92	149	(38)%	354	346	2 %
KANJINTI® — ROW	24	18	33 %	79	63	25 %
EPOGEN® — U.S.	138	149	(7)%	393	465	(15) %
EVENITY® — U.S.	94	54	74 %	230	131	76 %
EVENITY® — ROW	55	5	*	157	129	22 %
BLINCYTO® — U.S.	74	54	37 %	201	167	20 %
BLINCYTO® — ROW	51	35	46 %	139	109	28 %
AMGEVITA™ — ROW	111	80	39 %	324	228	42 %
Aimovig® — U.S.	77	105	(27)%	225	274	(18) %
Aimovig® — ROW	2	—	NM	2	—	NM
Parsabiv® — U.S.	24	156	(85)%	107	462	(77) %
Parsabiv® — ROW	37	27	37 %	104	82	27 %
NEUPOGEN® — U.S.	32	44	(27)%	86	117	(26) %
NEUPOGEN® — ROW	20	21	(5)%	51	62	(18) %
Sensipar® — U.S.	—	7	(100)%	4	81	(95) %
Sensipar®/Mimpara™ — ROW	19	32	(41)%	62	162	(62) %
LUMAKRAS® — U.S.	33	—	NM	42	—	NM
LUMYKRAS™ — ROW	3	—	NM	3	—	NM
Other — U.S.	61	31	97 %	141	78	81 %
Other — ROW	32	52	(38)%	92	129	(29) %
Total other products	$ 1,726	$ 1,655	4 %	$ 5,033	$ 4,816	5 %
Total U.S. — other products	$ 1,052	$ 1,142	(8)%	$ 3,059	$ 3,164	(3) %
Total ROW — other products	674	513	31 %	1,974	1,652	19 %
Total other products	$ 1,726	$ 1,655	4 %	$ 5,033	$ 4,816	5 %

NM - Not meaningful

* - 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,		
	2021	2020	Change	2021	2020	Change
Operating expenses:						
Cost of sales	$ 1,609	$ 1,561	3 %	$ 4,736	$ 4,562	4 %
% of product sales	25.5 %	25.6 %		26.3 %	25.5 %	
% of total revenues	24.0 %	24.3 %		24.8 %	24.3 %	
Research and development	$ 1,422	$ 1,062	34 %	$ 3,471	$ 2,978	17 %
% of product sales	22.5 %	17.4 %		19.3 %	16.6 %	
% of total revenues	21.2 %	16.5 %		18.1 %	15.8 %	
Acquired in-process research and development	$ —	$ —	— %	$ 1,505	$ —	NM
% of product sales	— %	— %		8.3 %	— %	
% of total revenues	— %	— %		7.9 %	— %	
Selling, general and administrative	$ 1,305	$ 1,346	(3) %	$ 3,943	$ 3,957	— %
% of product sales	20.6 %	22.1 %		21.9 %	22.1 %	
% of total revenues	19.5 %	21.0 %		20.6 %	21.1 %	
Other	$ (8)	$ 1	*	$ 143	$ 162	(12) %

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NM - Not meaningful

* - Change in excess of 100%

Cost of sales

Cost of sales decreased to 24.0% of total revenues for the three months ended September 30, 2021, primarily driven by lower amortization expense from acquisition-related assets, offset by unfavorable product mix.

Cost of sales increased to 24.8% of total revenues for the nine months ended September 30, 2021, primarily driven by unfavorable product mix, partially offset by lower amortization expense from acquisition-related assets.

Research and development

The increase in R&D expense for the three months ended September 30, 2021, was driven by a licensing-related upfront payment to KKC, partially offset by lower late-stage support for existing programs.

The increase in R&D expense for the nine months ended September 30, 2021, was primarily driven by a licensing-related upfront payment to KKC and higher research and early pipeline spend, partially offset by lower late-stage support for existing programs.

Acquired in-process research and development

Acquired IPR&D expense for the nine months ended September 30, 2021, is related to the bemarituzumab program acquired as part of the Five Prime acquisition.

Selling, general and administrative

The decrease in Selling, general and administrative (SG&A) expense for the three months ended September 30, 2021, was primarily driven by lower spend in general and administrative activities.

The decrease in SG&A expense for the nine months ended September 30, 2021, was primarily driven by lower spend in general and administrative activities and favorable adjustments to estimated U.S. healthcare reform federal excise fees, partially offset by higher marketed-product support and investment in new launches.

Other

Other operating expenses for the three months ended September 30, 2021, consisted primarily of changes in the fair values of contingent consideration liabilities. Other operating expenses for the nine months ended September 30, 2021, consisted primarily of expenses related to cost savings initiatives.

Other operating expenses for the nine months ended September 30, 2020, consisted of legal settlement expenses.

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,	
	2021	2020	2021	2020
Interest expense, net	$ (296)	$ (302)	$ (862)	$ (944)
Other income, net	$ 73	$ 55	$ 97	$ 69
Provision for income taxes	$ 271	$ 185	$ 576	$ 607
Effective tax rate	12.6 %	8.4 %	12.6 %	9.7 %

Interest expense, net

The decrease in Interest expense, net, for the three months ended September 30, 2021, was primarily due to lower LIBOR rates in the current year period on debt for which we effectively pay a variable rate of interest through the use of interest rate swaps, partially offset by higher overall debt outstanding in the current year period.

The decrease in Interest expense, net, for the nine months ended September 30, 2021, was primarily due to net costs associated with the early retirement of debt in the first quarter of the prior year and lower LIBOR rates in the current year period on debt for which we effectively pay a variable rate of interest through the use of interest rate swaps, partially offset by higher overall debt outstanding in the current year period.

Other income, net

The increase in Other income, net, for the three and nine months ended September 30, 2021, was primarily due to net gains recognized on our strategic equity investments, partially offset by higher losses in connection with our BeiGene investment.

Income taxes

The increase in our effective tax rate for the three and nine months ended September 30, 2021, was primarily due to the non-deductible IPR&D expense arising from the acquisition of Five Prime and prior year favorable items partially offset by a change in earnings mix.

The Administration and Congress are considering significant changes to existing tax law, including an increase in the corporate tax rate and the tax rate on foreign earnings. These changes could substantially increase U.S. taxation of our operations both in and outside the United States, including the U.S. territory of Puerto Rico. In addition, the Organisation for Economic Co-operation and Development (OECD) recently reached agreement to align countries on a minimum corporate tax rate and an expansion of the taxing rights of market countries. If enacted, this agreement could result in tax increases in both the United States and foreign jurisdictions.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010, 2011 and 2012 proposing 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. We disagreed with the proposed adjustments and calculations and pursued a resolution with the IRS administrative appeals office. As previously reported, we were unable to reach resolution with the IRS appeals office. In July 2021, we filed a petition in the U.S. Tax Court to contest two duplicate Notices for 2010, 2011 and 2012 that we received in May and July 2021. The duplicate Notices seek to increase our U.S. taxable income by an amount that would result in additional federal tax of approximately $3.6 billion, plus interest. Any additional tax that could be imposed would be reduced by up to approximately $900 million of repatriation tax previously accrued on our foreign earnings. In any event, we firmly believe that the IRS's positions in the Notices are without merit, and we will vigorously contest the Notices through the judicial process.

In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing 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, similar to those proposed for the years 2010, 2011 and 2012. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. As a consequence of the Tax Court litigation for the 2010-2012 period, the IRS administrative appeals office recently informed us that it does not plan to engage in discussions at this time regarding the allocation of profits between our entities in the United States and the U.S. territory of Puerto Rico for the 2013-2015 period. We are currently under examination by the IRS for the years 2016, 2017 and 2018. 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. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued as noted above and could have a material adverse impact on our condensed consolidated financial statements.

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

Financial condition, liquidity and capital resources

Selected financial data were as follows (in millions):

	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 12,921	$ 10,647
Total assets	$ 64,993	$ 62,948
Current portion of long-term debt	$ 4,288	$ 91
Long-term debt	$ 33,291	$ 32,895
Stockholders' equity	$ 8,217	$ 9,409

Cash, cash equivalents and marketable securities

Our balance of cash, cash equivalents and marketable securities was $12.9 billion at September 30, 2021. 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 issued by institutions with investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

Capital allocation

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 and our desire to optimize our cost of capital. 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.

In July 2021, March 2021 and December 2020, the Board of Directors declared a quarterly cash dividend of $1.76 per share of common stock, which were paid on September 8, 2021, June 8, 2021 and March 8, 2021, respectively, an increase of 10% over the quarterly cash dividend paid in each quarter in 2020. In October 2021, the Board of Directors declared a quarterly dividend of $1.76 per share, which will be paid on December 8, 2021.

We also returned capital to stockholders through our stock repurchase program. During the nine months ended September 30, 2021, we executed trades to repurchase $3.5 billion of common stock. As of September 30, 2021, $2.9 billion of authorization remained available under our stock repurchase program. In October 2021, the Board of Directors increased the amount authorized under our stock repurchase program by an additional $4.5 billion.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of September 30, 2021 and December 31, 2020. Our accumulated deficit is not anticipated 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, to meet capital expenditure and debt service requirements, to fund our plans to pay dividends and repurchase stock and to fulfill other business initiatives we expect 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, equity markets and borrowings (including commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt markets). See our Annual Report on Form 10-K for the year ended December 31, 2020, 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 that requires us to 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, 2021.

Cash flows

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

	Nine months ended September 30,	
	2021	2020
Net cash provided by operating activities	$ 6,453	$ 8,344
Net cash provided by (used in) investing activities	$ 963	$ (4,017)
Net cash used in financing activities	$ (1,713)	$ (1,277)

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, 2021, decreased primarily due to (i) the monetization of interest rate swaps in the prior year, (ii) a difference in the timing of payments to tax authorities and sales deductions paid to customers, (iii) lower Net income, after adjustments for noncash items and (iv) the timing of collections from customers.

Investing

Cash provided by investing activities during the nine months ended September 30, 2021, was primarily due to net cash inflows related to marketable securities of $3.4 billion, partially offset by the acquisition of Five Prime for $1.6 billion, net of cash acquired, and capital expenditures of $593 million. Cash used in investing activities during the nine months ended September 30, 2020, was due to our $3.2 billion of equity investments, primarily BeiGene, capital expenditures of $435 million and net cash outflows related to marketable securities of $394 million. We currently estimate 2021 spending on capital projects to be approximately $900 million.

Financing

Cash used in financing activities during the nine months ended September 30, 2021, was primarily due to payments to repurchase our common stock of $3.5 billion and the payment of dividends of $3.0 billion, partially offset by proceeds from the issuance of debt of $4.9 billion. Cash used in financing activities during the nine months ended September 30, 2020, was primarily due to the payment of dividends of $2.8 billion and payments to repurchase our common stock of $2.3 billion, partially offset by proceeds from the issuance of debt, net of repayments, of $3.9 billion. See Note 10, Financing arrangements, and Note 11, Stockholders' equity, to the condensed consolidated financial statements for further discussion.

Critical accounting policies

The preparation of our condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore actual results could differ materially from those estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2020.

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, 2020, and is incorporated herein by reference. Except as discussed below, there were no material changes during the nine months ended September 30, 2021, 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, 2020.

Interest rate sensitive financial instruments

To achieve a desired mix of fixed and floating interest rate debt, we entered into additional interest rate swap contracts with an aggregate notional amount of $1.5 billion during the three months ended June 30, 2021. As of September 30, 2021, an aggregate notional amount of $7.4 billion of interest rate swap contracts was outstanding. These interest rate swap contracts effectively converted a fixed-interest-rate coupon to a floating-rate LIBOR-based coupon over the life of the respective notes. A hypothetical 100-basis-point increase in interest rates relative to interest rates at September 30, 2021, would have resulted in a reduction in fair value of approximately $370 million on our interest rate swap contracts on that date. The analysis of the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair value of debt that these interest-rate-sensitive instruments were designed to offset.

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 gets recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information gets 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 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 on 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, 2021.

Management determined that as of September 30, 2021, no changes in our internal control over financial reporting had occurred during the fiscal quarter then ended that materially affected or are reasonably likely to materially affect our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

See Notes 12, 13 and 14, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2021, June 30, 2021 and September 30, 2021, respectively, 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, 2020.

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. These statements are not guarantees of future performance, and they involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties 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 provide 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, 2020, provide additional disclosure for these supplemental risks and are incorporated herein by reference.

RISKS RELATED TO ECONOMIC CONDITIONS AND OPERATING A GLOBAL BUSINESS, INCLUDING DURING THE COVID-19 PANDEMIC

The COVID-19 pandemic, and the effort to mitigate 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, manufacturing, 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 are expected to continue to adversely affect, our business (including our R&D, clinical trials, operations, manufacturing, supply chains, distribution systems, product development and sales activities), the business activities of our suppliers, customers, third-party payers and our patients. See our Annual Report on Form 10-K for the year ended December 31, 2020, Part I, Item 1A. Risk Factors—*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*; see also *Our current products and products in development cannot be sold without regulatory approval*; and see also *We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications*. 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, exacerbated by COVID-19 surges resulting in repeated shutdowns and/or disruptions in certain geographies.

Federal, state and local, and international governmental policies and initiatives designed to reduce the transmission of COVID-19 also have resulted in the cancellation or delay 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. For example, a recent NPR/Harvard poll found that, with hospitals crowded from COVID-19, one in five U.S. households has had to delay care for serious illnesses in the past few months. These measures and challenges will likely continue to varying degrees for the duration of the pandemic and have significantly reduced patient access to, and administration of, certain of our drugs. For example, Prolia® requires 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 therapies that are less immunosuppressive or

therapies that do not require administration in a hospital setting, potentially adversely affecting certain of our products. Also, new patients have been, and are expected to continue to be, less likely to be diagnosed and/or to start therapeutics during the pandemic, and these effects, together with the lower treatment rates during the pandemic, have had, and are expected to continue to have, a cumulative negative effect on the commercial performance of our business. The decrease in diagnoses over the course of the pandemic has suppressed the volume of new patients starting treatment, which we expect to continue to impact our business for the remainder of the year. Once the pandemic subsides, we anticipate there could be a 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 lower provider capacity, and this lower 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.

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 development, operational and commercial activities, customer purchases and our collections of accounts receivable. It remains uncertain the degree to which these adverse effects would impact our future operational and commercial activities, customer purchases and our collections as conditions begin to improve. There has been a resurgence in COVID-19 infections in numerous jurisdictions to date in 2021, resulting in the reinstatement of stricter restrictions and shutdowns in a number of jurisdictions, including in the United States., Europe and Asia Pacific regions. It is expected that the pandemic will continue to ebb and flow, with different jurisdictions having higher levels of infections than others over the course of the pandemic. New variants of the SARS-CoV-2 virus have emerged, including the delta variant, and have been shown to be present in many geographies, and appear to spread more easily and quickly than other variants. Further, although some studies suggest that antibodies generated with currently authorized vaccines may be effective against these variants, it remains uncertain whether currently available vaccines will retain their efficacy against future variants of the virus. Further, even while vaccine booster shots are available for certain patients, persistent vaccine hesitancy may result in under-vaccinated populations which may prolong the duration of the COVID-19 pandemic and continue to disrupt the availability of healthcare services to the patients we serve. Jurisdictions may implement, 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 further prevent or discourage patients from participating in our clinical trials, 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. In the United States, on January 21, 2021, President Biden issued an Executive Order instructing federal agencies to use all available legal authorities, including the Defense Production Act, to improve current and future pandemic response and biological threat preparedness. The rapid reallocation of resources for the treatment and prevention of COVID-19 (including the production of COVID-19 vaccinations or related therapies, such as our agreement to contribute to the production of COVID-19 antibody therapies for Eli Lilly and Company) and/or disruptions and shortages in the global supply chain caused by the pandemic, could also result in increased competition for, or reduced availability of, materials or components used in the development, manufacturing, distribution, or administration of our products. For example, during the second quarter of 2021, an industry-wide shortage of certain lab kit supplies necessary for some activities that support our clinical trials has developed that we are actively monitoring and managing. 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, 2020, 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 United States and China or other governments deteriorates, our business and investments in China or other such markets may also be adversely affected. See our Annual Report on Form 10-K for the year ended December 31, 2020, Part I, Item 1A. Risk Factors—*Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.*

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 (including the distribution and/or availability of vaccines), and the extent to which such measures are effective, if at all, remain highly uncertain. The magnitude and degree of COVID-19's adverse effect on our business (including our product development,

product sales, operating results and resulting 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 mitigation of the pandemic continues to require further shelter-in-place and shutdown orders and/or restrictions on individual and/or group conduct, any adverse effects of the COVID-19 pandemic will likely grow and could be enduring and our business and financial position could be materially adversely affected.

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

To achieve our business objectives, we rely on sophisticated information technology systems, including software, mobile applications, cloud services and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or adversely affect our reputation.

Our information technology systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. Further, as the majority of our employees are working remotely, our reliance on our and third-party information technology systems has increased substantially and is expected to continue to increase. The complexity and interconnected nature of our systems makes them potentially vulnerable to breakdown or other service interruptions. Upgrades or changes to our systems or the software that we use may result in the introduction of new cybersecurity vulnerabilities and risks. Our systems are also subject to frequent cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity and are becoming increasingly difficult to detect. Such attacks could include the use of harmful and virulent malware, including ransomware or other denials of service, that can be deployed through various means, including the software supply chain, e-mail, malicious websites and/or the use of social engineering. We have also experienced unsuccessful denial of service attacks against our network, and although such attacks did not succeed, there can be no assurance that our efforts to guard against the wide and growing variety of potential attack techniques will be successful in the future. Attacks such as those experienced by governmental entities (including those that approve and/or regulate our products, such as the European Medicines Agency (EMA)) and other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access or protect important data, and could have a material adverse effect on our ability to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and/or distributing our products. For example, in 2017, a pharmaceutical company experienced a cyberattack involving virulent malware that significantly disrupted its operations, including its research and sales operations and the production of some of its medicines and vaccines. As a result of the cyberattack, its orders and sales for certain products in certain markets were negatively affected. In December 2020, SolarWinds Corporation, a leading provider of software for monitoring and managing information technology infrastructure, disclosed that it had suffered a cybersecurity incident whereby attackers had inserted malicious code into legitimate software updates for its products that were installed by myriad private and government customers, enabling the attackers to access a backdoor to such systems. See our Annual Report on Form 10-K for the year ended December 31, 2020, Part I, Item 1A. Risk Factors—*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* for a discussion of the cyberattack on the EMA.

Our systems also contain and utilize a high volume of sensitive data, including intellectual property, trade secrets, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials and/or personal information belonging to us, our staff, our patients, customers and/or other parties. In some cases, we utilize third-party service providers to process, store, manage or transmit such data, which may increase our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) resulting from attacks or lapses by employees, service providers (including providers of information technology-specific services), nation states (including groups associated with or supported by foreign intelligence agencies), organized crime organizations, "hacktivists" or others, create risks that our sensitive data may be exposed to unauthorized persons, our competitors, or the public. For example, a supplier recently experienced a data breach in which an unauthorized third party acquired access to certain information provided to the supplier in the course of its provision of services to us, including business documents and certain personally identifiable patient information (not including social security or other financial or health insurance information). As required, we promptly notified the applicable state attorneys general and the individuals whose personally identifiable information was affected of this data breach at the supplier. Although the supplier data breach did not result in a material adverse effect on our business, there can be no assurance that a similar future cybersecurity incident would not result in a material adverse effect on our business or results of operations. Another vendor experienced a cyberattack and, while initially reporting that our information was not involved, the vendor subsequently informed us that the attacker had accessed limited, non-significant information. Although this breach did not have a significant

adverse effect on us, we may not receive timely reporting of future breaches.

Domestic and global government regulators, our business partners, suppliers with whom we do business, companies that provide us or our partners with business services, and companies we have or may acquire face similar risks, and security breaches of their systems or service outages could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data or sensitive personal information. For example, in 2019, two vendors that perform testing and analytical services that we use in developing and manufacturing our products have experienced cyberattacks, and in April and September of 2020, vendors that provide us with information technology services and clinical data services, respectively, each experienced ransomware attacks. Although there was no breach of our systems, each of these incidents required us to disconnect our systems from those vendors' systems. While we were able to reconnect our systems following restoration of these vendors' capabilities without significantly affecting product availability, a more extended service outage affecting these or other vendors, particularly where such vendor is the single source from which we obtain the services, could have a material adverse effect on our business or results of operations. In addition, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers and patients.

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

We are also subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and developing and the subject of significant attention globally. For example, we are subject to the European Union's General Data Protection Regulation, which became effective in May 2018, and the California Consumer Privacy Act of 2018 (CCPA), which became effective in January 2020, both of which provide for substantial penalties for non-compliance. The CCPA was amended in late 2020, to create the California Privacy Rights Act to create opt-in requirements for the use of sensitive personal data and the formation of a new dedicated agency for the enforcement of the law, the California Privacy Protection Agency. Since then, Virginia and Colorado both passed similar consumer privacy laws that will go into effect in 2023. Other jurisdictions where we operate continue to propose similar legislation and/or regulations with others expected to pass in 2021. Failure to comply with these current and future laws could result in significant penalties and reputational harm and could have a material adverse effect on our business and results of operations.

RISKS RELATED TO GOVERNMENT REGULATIONS AND THIRD-PARTY POLICIES

Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.

Sales of our products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers continue to pursue initiatives to manage drug utilization and contain costs. These payers are increasingly focused on the effectiveness, benefits and costs of similar treatments, which have resulted, and are expected to continue to result, in lower reimbursement rates for our products or narrower populations for whom payers will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payer dynamics, have limited, and are likely to continue to limit, our ability to set or adjust the price of our products based on their value, which can have a material adverse effect on our business. In the United States, particularly over the past few years, a number of legislative and regulatory proposals have been introduced in an attempt to lower drug prices. These include proposals that would allow the U.S. government to negotiate drug prices directly, limit drug reimbursement in Medicare and/or the commercial market based on a reference prices or permit importation of drugs from Canada. Additional proposals would require a rebate to the government for any price increase in excess of the Consumer Price Index for All Urban Consumers and/or to shift some of the costs of these Medicare Part D reforms to manufacturers to offset the cost. Proposals focused on drug pricing have been implemented and are likely to continue to be proposed and may be adopted and implemented in some form. See our Annual Report on Form 10-K for the year ended December 31, 2020, Part I, Item 1A. Risk Factors—*Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.*

—Changing U.S. federal coverage and reimbursement policies and practices have affected and may continue to affect access to, pricing and sales of our products

A substantial portion of our U.S. business relies on reimbursement from federal government healthcare programs and commercial insurance plans regulated by federal and state governments. See our Annual Report on Form 10-K for the year ended December 31, 2020, Part I, Item 1. Business—Reimbursement. Our business has been and will continue to be affected by legislative actions changing U.S. federal reimbursement policy. Congress has been focused on drug pricing reforms and oversight since 2018, and is ongoing. For example, in 2020, Amgen participated in House Oversight and Reform Committee hearings on drug pricing practices. Additionally, in 2019 and 2020, a number of other Congressional committees debated drug pricing reform proposals. For example, in 2019, the Senate Finance Committee advanced a bill that would, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and/or D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries and require higher/additional manufacturer discounts in Medicare Part D. Additionally, in late 2019, a drug-pricing bill, H.R. 3, passed the House of Representatives, which would, among other things, enable direct price negotiations by the federal government on certain drugs (with the maximum price paid by Medicare capped by prices derived from an international index), includes a penalty for failing to reach agreement with the government and requires that manufacturers offer these negotiated prices to other payers. Further, proposals from H.R. 3 have been incorporated into other proposed legislation, including the House's drug pricing provisions based on H.R. 3 in the Build Back Better reconciliation bill, and proposals from H.R. 3 are also likely to be included in the version of the reconciliation bill that remains to be further debated between the House, Senate and White House. Other legislation has also contained drug pricing reforms, including the Infrastructure Investment and Jobs Act passed by the Senate in August 2021, which includes a provision that would, starting in 2023, require manufacturers to provide Medicare with rebates for certain drugs paid under Medicare Part B, and the American Rescue Plan Act of 2021, which includes a provision, to be implemented in 2024, that increases the Medicaid rebate liability for certain medicines that raise prices in excess of inflation. On November 2, 2021, Congress announced a framework for drug pricing reform that includes inflation penalties, Medicare negotiation for select drugs paid for under Parts B and D, and a Medicare Part D redesign. As of the date of this filing, this framework remains in discussion with policymakers in Congress and the Administration.

There are other outstanding proposals that have been introduced by the prior Administration that, if enacted and implemented in whole or in part, could also affect access to and sales of our products, including, but not limited to, proposals to allow importation of prescription medications from Canada or other countries and to set Medicare payment rates using international price referencing. Further, in mid-2020, the prior Administration announced a number of Executive Orders intended to reduce the cost of biopharmaceuticals for patients, including a most favored nation (MFN) policy for Medicare Parts B and D, under which the Health & Human Services (HHS) was 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 Part B and Part D medicines. In September 2020, in response to the corresponding Executive Order, HHS released a final rule to allow states (or other nonfederal government entities) to submit proposals to the FDA allowing for the importation of certain nonbiologic prescription drugs from Canada. Currently, the rule is being challenged by litigation, however, should such litigation be unsuccessful and should the Secretary of HHS authorize state proposals for importation, this rule could allow the importation of Canadian versions of certain of Amgen's products (including Otezla®), that could have a material adverse effect on Amgen's business. Further, in November 2020, also in response to the corresponding Executive Order, HHS released an interim final rule to implement the MFN pricing approach. If implemented, the MFN rule would set the reimbursement rate for 50 Medicare Part B drugs (including our products, such as Prolia®, XGEVA®, KYPROLIS®, Neulasta®, Nplate®, EPOGEN® and Aranesp®) equal to the lowest adjusted price for such products of the 22 OECD nations. Lawsuits have been filed by certain trade groups challenging the implementation of this MFN rule based on, among other things, procedural defects. Late in 2020, in the case filed by the Biotechnology Innovation Organization (BIO) and others, the U.S. District Court for the Northern District of California issued a preliminary injunction preventing the rule from taking effect nationwide, pending the government's completion of required administrative procedures. The case was subsequently stayed by the court and will remain stayed until at least November 10, 2021, when the parties will be required to submit a joint status report to the court. Another case, filed by the Pharmaceutical Research and Manufacturers of America and others in the U.S. District Court for the District of Maryland, was also stayed until either a final rule based on the MFN interim rule is published in the Federal Register, or until the court orders a lifting of the stay based on, among other things, the status of the nationwide preliminary injunction issued in the BIO case. In August 2021, Centers for Medicare & Medicaid Services (CMS) released a proposal to withdraw the MFN rule, noting, however, that the proposal to withdraw "does not reflect any judgment by HHS regarding future policy." Notwithstanding these stays and the proposed withdrawal of the rule, the MFN rule's approach to drug pricing and other similar approaches remain of interest. Further, despite the change in Administration, we expect continued significant focus on healthcare and similar drug pricing proposals for the foreseeable future, including proposals similar to the MFN rule or other proposals that would grant the HHS secretary the authority to negotiate drug prices directly with manufacturers. On July 9, 2021, the Administration issued an Executive Order designed to address anticompetitive behavior across multiple sectors, and for the healthcare sector, called for, among other things, more scrutiny of anticompetitive activity by the Federal Trade

Commission (FTC), emphasized the need for actions to allow for greater competition from generics and biosimilars, and called for the FDA to work with states and Indian Tribes to develop prescription drug importation programs. The Executive Order established a process and timeline for federal agencies to deliver ideas on drug pricing to the Administration, including requiring HHS to develop a comprehensive plan within 45 days to address drug pricing. Subsequently, on September 9, 2021, the HHS released a report that presented guiding principles for the Administration's drug pricing proposals, including changes to promote competition throughout the prescription drug industry, highlighting potential legislative policies that Congress could pursue (including drug price negotiation in Medicare Parts B and D, making those negotiated prices available to commercial plans and legislation to speed the entry of biosimilar and generic drugs) and examples of potential administrative tools available to the HHS (including various testing models and enhanced focus of the FTC and the USPTO to address impediments to generic drug and biosimilar competition). Also in response to the July 9 Executive Order, the FDA sent a letter to the USPTO describing ways to strengthen coordination between the two agencies, offered training to help identify prior art, and seeking USPTO's views on practices that extend market exclusivities, whether pharmaceutical patent examiners need additional resources, and the effect of post-grant challenges at the PTAB on drug patents.

Our business has been, and is expected to continue to be, affected by changes in U.S. federal reimbursement policy resulting from federal regulations and federal demonstration projects. Over the past three years, federal agencies, including the CMS, announced a number of recommendations, policies, proposals and demonstration projects addressing drug pricing. CMS is the federal agency responsible for administering Medicare and overseeing state Medicaid programs and Health Insurance Marketplaces and has substantial power to implement policy changes or demonstration projects that can quickly and significantly affect how drugs, including our products, are covered and reimbursed. CMS issued guidance to allow certain Medicare plans offered by private insurance companies to require that patients receiving Medicare Part B drugs first try a drug preferred by the plan before covering another therapy (Step Therapy) and lowered reimbursement rates for new Medicare Part B drugs. Further, HHS issued a final rule under Medicare Part D revising the regulations under the federal antikickback statute to encourage Pharmacy Benefit Managers (PBMs) to use rebates received from biopharmaceutical manufacturers to reduce patient cost-sharing at the point of sale. While the implementation date for the rule is January 1, 2023, the rule remains subject to litigation, there are numerous logistical hurdles to overcome before it can be effectively implemented, and it is unclear how PBMs will respond and what the current Administration's position is on the rule. Further, while the prior Administration finalized a rule (effective January 1, 2022) mandating price and cost-sharing transparency for almost all health plans and insurers in the individual and group commercial markets, the current Administration has delayed implementation of those drug price transparency provisions and has indicated that there will be future rulemaking on the issue. It is unclear how group health plans and health insurers may respond. The Administration also could develop and seek to advance a range of policy proposals that could impact U.S. federal reimbursement policy for drugs and biologics, including changes to Medicare Part B.

CMS policy changes and demonstration projects to test new care, delivery and payment models can significantly affect how drugs, including our products, are covered and reimbursed. In end-stage renal disease (ESRD), CMS uses bundled payment rates. Between 2018 and 2020, Sensipar® and Parsabiv®, our calcimimetics that are used in dialysis clinics, were eligible for temporary drug add-on payment adjustments (TDAPA) to the bundled rate. In November 2020, CMS released its final rule ending the TDAPA for calcimimetics and adjusting ESRD Prospective Payment System bundled rates on January 1, 2021 by $9.93 per dialysis treatment for calcimimetics. As a result, sales of Parsabiv® have been materially adversely affected by this rule change. Additionally, CMS created a new mandatory payment model, effective January 1, 2021, focused on encouraging greater use of home dialysis and kidney transplants for ESRD patients that could result in changes to treatment of dialysis patients, including reduction of the use of our ESAs. Further, in November 2019, CMS announced additional voluntary payment models for nephrologists and dialysis facility partners that also seek to encourage home dialysis and preemptive transplantation through increased risk sharing, effective January 1, 2022. CMS has also solicited suggestions regarding other potential care models. In 2016, CMS initiated the Oncology Care Model demonstration, which provides participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare costs without negatively affecting the efficacy of care, that has been extended by one year (to 2022) due to COVID-19. We believe the Oncology Care Model has reduced utilization of certain of our oncology products by participating physician practices and expect it to continue to do so in the future. Additionally, in late 2019, CMS announced a request for information on the Oncology Care First model, a new voluntary model that builds on the Oncology Care Model. CMS has indicated a continued interest in exploring demonstrations of mandatory models, and may propose both new mandatory payment models in the future that could adversely affect our business. For example, HHS's September 2021 comprehensive plan to address drug pricing included potential future mandatory models that link payment for prescription drugs and biologics to factors such as: improved patient outcomes, reductions in health disparities, patient affordability, and lower overall costs; bundled payment models; total cost of care models; models in which Medicare Part B savings from utilization of biosimilars, generics, or other high-value products are shared between prescribing providers and the government; models that provide additional Medicare Part D cost-sharing support for biosimilars and generics; and potential expansion of the Part D Senior Savings Model to additional classes of drugs. CMS recently finalized a rule that, starting January 1, 2023, unless a manufacturer can ensure that the full amount of manufacturer patient assistance programs is passed on to the patient, such amount will be treated as a price reduction that will be taken into account when

reporting our Best Price and/or Average Manufacturer Price. Given the use by PBMs and insurers of copay accumulator adjustment programs to apply such patient assistance for the benefit of such companies and not to defray costs to patients, it could be difficult to impossible for manufacturers to ensure that the full value of such amounts is being passed on to the patient. This new policy, if implemented, would have significant implications for our ability to offer copay assistance programs. In this dynamic environment, particularly in light of the pressures on healthcare budgets as a result of the pandemic, we are unable to predict which or how many federal policy, legislative, regulatory, executive or administrative changes may ultimately be, or effectively estimate the consequences to our business if, enacted and implemented. However, to the extent that these or other federal government initiatives further decrease or modify the coverage or reimbursement available for our products, require that we pay increased rebates or shift other costs to us, limit or affect our decisions regarding the pricing of or otherwise reduce the use of our U.S. products, or limit our ability to offer co-pay payment assistance to commercial patients, such actions could have a material adverse effect on our business and results of operations.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products. U.S. government price reporting regulations are complex and may require a biopharmaceutical manufacturer to update certain previously submitted data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data, we also may be required to pay additional rebates and provide additional discounts.

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.

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 can 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, and such tax authorities (including the IRS) are becoming more aggressive in their audits and are particularly focused on such matters. In 2017, we received a RAR and a modified RAR from the IRS for the years 2010, 2011 and 2012 proposing 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. As previously reported, we disagreed with the proposed adjustments and calculations and pursued a resolution with the IRS administrative appeals office. However, we were unable to reach resolution with the IRS appeals office. In July 2021, we filed a petition in the U.S. Tax Court to contest two duplicative Notices for 2010, 2011 and 2012 that we received in May and July 2021 which seek to increase our U.S. taxable income. We firmly believe that the IRS's positions set forth in the Notices are without merit, and we will vigorously contest the Notices through the judicial process. See Note 4, Income taxes, to the condensed consolidated financial statements.

In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing 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 similar to those proposed for the years 2010, 2011 and 2012. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. As a consequence of the 2010-2012 Tax Court litigation, the IRS administrative appeals office recently informed us that it does not plan to engage in discussions at this time regarding the allocation of profits between our entities in the United States and the U.S. territory of Puerto Rico for the 2013-2015 period. We are currently under examination by the IRS for the years 2016, 2017 and 2018. 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. We continue to believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse effect on the results of our operations.

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 and could be subject to different interpretations. We could face audit challenges to our application of the 2017 Tax Act. The Administration and Congress are considering significant changes to existing tax law, including an increase in the corporate tax

rate and the tax rate on foreign earnings. These changes could substantially increase U.S. taxation of our operations both in and outside the United States, including the U.S. territory of Puerto Rico. Further, the OECD recently reached agreement to align countries on a minimum corporate tax rate and an expansion of the taxing rights of market countries. If enacted, this agreement could result in tax increases in both the United States and foreign jurisdictions. Changes to existing tax law in the United States, the U.S. territory of Puerto Rico, or other jurisdictions that would likely result in tax increases where we do business and could have a material adverse effect on the results of our operations.

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

During the three months ended September 30, 2021, 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	1,763,784	$ 245.52	1,763,784	$ 3,486,312,736
August 1 - 31	1,250,282	$ 226.31	1,250,282	$ 3,203,364,954
September 1 - 30	1,624,898	$ 217.23	1,624,898	$ 2,850,385,563
Total	4,638,964	$ 230.43	4,638,964	

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

(2) In March 2021, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $3.4 billion. In October 2021, the Board of Directors increased the amount authorized under our stock repurchase program by an additional $4.5 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.)
2.6	Agreement and Plan of Merger, dated as of March 4, 2021, by and among Amgen Inc., Franklin Acquisition Sub, Inc. and Five Prime Therapeutics, Inc. (Filed as an exhibit to Form 8-K on March 4, 2021 and incorporated herein by reference.)
2.7*	Agreement and Plan of Merger, dated July 27, 2021, by and among Amgen Inc., Teneobio, Inc., Tuxedo Merger Sub, Inc., and Fortis Advisors LLC. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential).
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 form of the Company's 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 15, 2020.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 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 15, 2020.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 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 15, 2020.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 and incorporated herein by reference.)
10.8+	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended and Restated on October 21, 2020.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 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 , 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	Amended and Restated Collaboration Agreement, dated June 2, 2021, 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). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2021 on August 4, 2021 and incorporated herein by reference.)
10.40	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.)
10.41	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.)
10.42	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.)
10.43	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.)
10.44	Restated Amendment No. 2 to Share Purchase Agreement, dated September 24, 2020, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2020 on October 29, 2020 and incorporated herein by reference.)
10.45	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.)
10.46	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.)

10.47	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.)
10.48	Amendment No. 7 to the Collaboration Agreement, dated December 18, 2020, by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC (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, 2020 on February 9, 2021 and incorporated herein by reference.)
10.49	License and Collaboration Agreement, dated June 1, 2021, by and between Amgen Inc. and Kyowa Kirin Co., 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-Q for the quarter ended June 30, 2021 on August 4, 2021 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: November 2, 2021

By: /S/ PETER H. GRIFFITH

Peter H. Griffith
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)