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

(Mark One)

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

For the quarterly period ended March 31, 2021

or

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

Commission File Number: 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value	**AMGN**	**The Nasdaq 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 April 22, 2021, the registrant had 574,553,986 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 March 31,	
	2021	2020
Revenues:		
Product sales	$ 5,592	$ 5,894
Other revenues	309	267
Total revenues	5,901	6,161
Operating expenses:		
Cost of sales	1,490	1,513
Research and development	967	952
Selling, general and administrative	1,254	1,316
Other	61	25
Total operating expenses	3,772	3,806
Operating income	2,129	2,355
Other income (expense):		
Interest expense, net	(285)	(346)
Other income, net	13	11
Income before income taxes	1,857	2,020
Provision for income taxes	211	195
Net income	$ 1,646	$ 1,825
Earnings per share:		
Basic	$ 2.85	$ 3.09
Diluted	$ 2.83	$ 3.07
Shares used in calculation of earnings per share:		
Basic	577	590
Diluted	581	594

See accompanying notes.

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

	Three months ended March 31,	
	2021	**2020**
Net income	$ 1,646	$ 1,825
Other comprehensive income (loss), net of reclassification adjustments and taxes:		
Losses on foreign currency translation	(39)	(52)
Gains (losses) on cash flow hedges	190	(61)
Losses on available-for-sale securities	—	(19)
Other gains (losses)	1	(2)
Other comprehensive income (loss), net of taxes	152	(134)
Comprehensive income	$ 1,798	$ 1,691

See accompanying notes.

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

	March 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,112	$ 6,266
Marketable securities	4,454	4,381
Trade receivables, net	4,423	4,525
Inventories	4,017	3,893
Other current assets	2,293	2,079
Total current assets	21,299	21,144
Property, plant and equipment, net	4,855	4,889
Intangible assets, net	15,947	16,587
Goodwill	14,673	14,689
Other assets	5,765	5,639
Total assets	$ 62,539	$ 62,948
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,396	$ 1,421
Accrued liabilities	9,917	10,141
Current portion of long-term debt	1,556	91
Total current liabilities	12,869	11,653
Long-term debt	31,129	32,895
Long-term tax liabilities	7,037	6,968
Other noncurrent liabilities	2,170	2,023
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding—575.3 shares in 2021 and 578.3 shares in 2020	31,806	31,802
Accumulated deficit	(21,639)	(21,408)
Accumulated other comprehensive loss	(833)	(985)
Total stockholders' equity	9,334	9,409
Total liabilities and stockholders' equity	$ 62,539	$ 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

	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

See accompanying notes.

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

	Three months ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net income	$ 1,646	$ 1,825
Depreciation, amortization and other	841	897
Deferred income taxes	(91)	(84)
Other items, net	79	107
Changes in operating assets and liabilities, net of acquisition:		
Trade receivables, net	91	(955)
Inventories	(126)	(113)
Other assets	(146)	319
Accounts payable	(29)	(25)
Accrued income taxes, net	52	137
Long-term tax liabilities	69	74
Other liabilities	(282)	(48)
Net cash provided by operating activities	2,104	2,134
Cash flows from investing activities:		
Purchases of marketable securities	(7,597)	(129)
Proceeds from sales of marketable securities	3,999	2,574
Proceeds from maturities of marketable securities	3,524	113
Purchases of property, plant and equipment	(166)	(142)
Purchases of equity method investments	—	(2,645)
Other	(79)	(1)
Net cash used in investing activities	(319)	(230)
Cash flows from financing activities:		
Net proceeds from issuance of debt	—	4,963
Repayment of debt	—	(3,250)
Repurchases of common stock	(871)	(961)
Dividends paid	(1,016)	(945)
Other	(52)	(61)
Net cash used in financing activities	(1,939)	(254)
(Decrease) increase in cash and cash equivalents	(154)	1,650
Cash and cash equivalents at beginning of period	6,266	6,037
Cash and cash equivalents at end of period	$ 6,112	$ 7,687

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 months ended March 31, 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.

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 $9.1 billion and $9.0 billion as of March 31, 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 impact that both standards will have on our condensed consolidated financial statements.

2. Revenues

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

Revenues were as follows (in millions):

	Three months ended March 31,					
	2021			2020		
	U.S.	ROW	Total	U.S.	ROW	Total
Enbrel® (etanercept)	$ 894	$ 30	$ 924	$ 1,117	$ 36	$ 1,153
Prolia® (denosumab)	501	257	758	422	232	654
Neulasta® (pegfilgrastim)	421	61	482	534	75	609
Otezla® (apremilast)	366	110	476	377	102	479
XGEVA® (denosumab)	334	134	468	355	126	481
Aranesp® (darbepoetin alfa)	125	230	355	175	247	422
Repatha® (evolocumab)	139	147	286	124	105	229
KYPROLIS® (carfilzomib)	159	92	251	187	93	280
Other products	964	628	1,592	988	599	1,587
Total product sales[1]	$ 3,903	$ 1,689	5,592	$ 4,279	$ 1,615	5,894
Other revenues			309			267
Total revenues			$ 5,901			$ 6,161

[1] Hedging gains and losses, which are included in product sales, were not material for the three months ended March 31, 2021 and 2020.

3. Income taxes

The effective tax rates for the three months ended March 31, 2021 and 2020, were 11.4% and 9.7%, respectively.

The increase in our effective tax rate for the three months ended March 31, 2021 was primarily due to changes in the jurisdictional mix of earnings. The effective tax rates differ from the federal statutory rate primarily as a result of foreign earnings from the Company's operations conducted in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes, and are subject to 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 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 disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. However, we have been unable to reach resolution at the administrative appeals level. We anticipate that we will receive a Notice of Deficiency which we will vigorously contest 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 are pursuing resolution with the IRS administrative appeals office. 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 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 months ended March 31, 2021, the gross amounts of our unrecognized tax benefits (UTBs) increased $60 million as a result of tax positions taken during the current year. Substantially all of the UTBs as of March 31, 2021, if recognized, would affect our effective tax rate.

4. Earnings per share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which primarily include shares that may be issued under our stock option, restricted stock and performance unit award programs (collectively, dilutive securities), as determined by using the treasury stock method.

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

	Three months ended March 31,	
	2021	2020
Income (Numerator):		
Net income for basic and diluted EPS	$ 1,646	$ 1,825
Shares (Denominator):		
Weighted-average shares for basic EPS	577	590
Effect of dilutive securities	4	4
Weighted-average shares for diluted EPS	581	594
Basic EPS	$ 2.85	$ 3.09
Diluted EPS	$ 2.83	$ 3.07

For the three months ended March 31, 2021 and 2020, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

5. Investments

Available-for-sale investments

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

Types of securities as of March 31, 2021	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 103	$ 1	$ —	$ 104
U.S. Treasury bills	4,949	—	—	4,949
Money market mutual funds	4,668	—	—	4,668
Other short-term interest-bearing securities	—	—	—	—
Total interest-bearing securities	$ 9,720	$ 1	$ —	$ 9,721

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	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 5,267	$ 5,464
Marketable securities	4,454	4,381
Total interest-bearing securities	$ 9,721	$ 9,845

Cash and cash equivalents in the above table excludes bank account cash of $845 million and $802 million as of March 31, 2021 and December 31, 2020, respectively.

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

Contractual maturities	March 31, 2021	December 31, 2020
Maturing in one year or less	$ 9,705	$ 9,795
Maturing after one year through three years	16	50
Total available-for-sale investments	$ 9,721	$ 9,845

For the three months ended March 31, 2021, realized gains and losses on interest-bearing securities were not material. For the three months ended March 31, 2020, realized gains and losses on interest-bearing securities were $37 million and $4 million, respectively. 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 primarily issued by institutions with investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

Equity securities

We held investments in equity securities with readily determinable fair values (publicly traded securities) of $394 million and $477 million as of March 31, 2021 and December 31, 2020, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. For the three months ended March 31, 2021 and 2020, net unrealized losses on publicly traded securities were $56 million and $76 million, respectively. Realized gains and losses on publicly traded securities for the three months ended March 31, 2021 and 2020, were not material.

We held investments of $204 million and $203 million in equity securities without readily determinable fair values as of March 31, 2021 and December 31, 2020, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. Gains and losses recognized on these securities, including adjustments to the carrying values of these securities, were not material for the three months ended March 31, 2021 and 2020.

Equity method investments

Limited partnerships

We held limited partnership investments of $676 million and $496 million as of March 31, 2021 and December 31, 2020, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. These investments, primarily investment funds of early-stage biotechnology companies, are accounted for by using the equity method of accounting and are measured by using our proportionate share of the net asset values of the underlying investments held by the limited partnerships as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of March 31, 2021, unfunded additional commitments to be made for these investments during the next several years were not material. For the three months ended March 31, 2021 and 2020, net gains recognized from our limited partnership investments were $208 million and $20 million, respectively.

BeiGene

As of March 31, 2021, we had an ownership interest of approximately 20.4% in BeiGene, which is included in Other 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, as well as 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 months ended March 31, 2021, the carrying value of our equity investment was reduced by our share of BeiGene's net losses of $97 million and amortization of the basis difference of $42 million. In addition, during the three months ended March 31, 2021, the carrying value increased by $17 million from the impact of BeiGene ownership transactions. As of March 31, 2021, the carrying value and fair value of our investment in BeiGene totaled $2.8 billion and $6.5 billion, respectively. As of March 31, 2021, we believe the carrying value of our equity investment in BeiGene is fully recoverable.

6. Inventories

Inventories consisted of the following (in millions):

	March 31, 2021	December 31, 2020
Raw materials	$ 605	$ 486
Work in process	2,463	2,437
Finished goods	949	970
Total inventories	$ 4,017	$ 3,893

7. Goodwill and other intangible assets

Goodwill

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

	Three months ended March 31, 2021
Beginning balance	$ 14,689
Currency translation adjustment	(16)
Ending balance	$ 14,673

Other intangible assets

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

	March 31, 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	$ 25,578	$ (11,114)	$ 14,464	$ 25,591	$ (10,564)	$ 15,027
Licensing rights	3,766	(2,842)	924	3,743	(2,791)	952
Marketing-related rights	1,364	(1,059)	305	1,367	(1,041)	326
Research and development technology rights	1,301	(1,077)	224	1,317	(1,065)	252
Total finite-lived intangible assets	32,009	(16,092)	15,917	32,018	(15,461)	16,557
Indefinite-lived intangible assets:						
In-process research and development	30	—	30	30	—	30
Total other intangible assets	$ 32,039	$ (16,092)	$ 15,947	$ 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 up-front payments associated with royalty obligations for marketed products. Marketing-related rights primarily consists of rights related to the sale and distribution of marketed products. Research and development (R&D) technology rights pertains to technologies used in R&D that have alternative future uses.

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

During the three months ended March 31, 2021 and 2020, we recognized amortization associated with our finite-lived intangible assets of $654 million and $709 million, respectively. Amortization of intangible assets is primarily included in Cost of sales in the Condensed Consolidated Statements of Income. The total estimated amortization for our finite-lived intangible assets for the remaining nine months ending December 31, 2021, and the years ending December 31, 2022, 2023, 2024, 2025 and 2026, are $1.9 billion, $2.5 billion, $2.4 billion, $2.4 billion, $2.2 billion and $1.8 billion, respectively.

8. Financing arrangements

Our borrowings consisted of the following (in millions):

	March 31, 2021	December 31, 2020
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	$ 1,466	$ 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)	742	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)	880	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)	655	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
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	965	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
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
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
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	(1,182)	(1,188)
Fair value adjustments	391	566
Other	5	5
Total carrying value of debt	32,685	32,986
Less current portion	(1,556)	(91)
Total long-term debt	$ 31,129	$ 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.

9. 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

In March 2021, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $3.4 billion. As of March 31, 2021, $5.5 billion of authorization remained available under our stock repurchase program.

Dividends

In March 2021, the Board of Directors declared a quarterly cash dividend of $1.76 per share, which will be paid in June 2021. In December 2020, the Board of Directors declared a quarterly cash dividend of $1.76 per share, which was paid in March 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)

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

	Three months ended March 31,		
Components of AOCI	2021	2020	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract (losses) gains	$ (1)	$ 49	Product sales
Cross-currency swap contract losses	(132)	(133)	Other income, net
	(133)	(84)	Income before income taxes
	28	18	Provision for income taxes
	$ (105)	$ (66)	Net income
Available-for-sale securities:			
Net realized gains	$ —	$ 33	Other income, net
	—	(7)	Provision for income taxes
	$ —	$ 26	Net income

10. Fair value measurement

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

Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access
Level 2 — Valuations for which all significant inputs are observable either directly or indirectly—other than Level 1 inputs
Level 3 — Valuations based on inputs that are unobservable and significant to the overall fair value measurement

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

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

Fair value measurement as of March 31, 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	$ 104	$ —	$ —	$ 104
U.S. Treasury bills	4,949	—	—	4,949
Money market mutual funds	4,668	—	—	4,668
Other short-term interest-bearing securities	—	—	—	—
Equity securities	394	—	—	394
Derivatives:				
Foreign currency contracts	—	79	—	79
Cross-currency swap contracts	—	153	—	153
Interest rate swap contracts	—	33	—	33
Total assets	$ 10,115	$ 265	$ —	$ 10,380
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 107	$ —	$ 107
Cross-currency swap contracts	—	291	—	291
Interest rate swap contracts	—	134	—	134
Contingent consideration obligations	—	—	39	39
Total liabilities	$ —	$ 532	$ 39	$ 571

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 securities are based on quoted market prices in active markets, with no valuation adjustment.

Derivatives

All of our foreign currency forward derivative contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A– or equivalent by Standard & Poor's Financial Services LLC (S&P), Moody's Investors Service, Inc. (Moody's) or Fitch Ratings, Inc. (Fitch). We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. These inputs, when applicable, are at commonly quoted intervals. See Note 11, 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 11, 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 11, Derivative instruments.

During the three months ended March 31, 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 March 31, 2021 and December 31, 2020, the aggregate fair values of our borrowings were $36.7 billion and $39.4 billion, respectively, and the carrying values were $32.7 billion and $33.0 billion, respectively.

11. 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—primarily over a three-year time horizon, with, at any given point in time, a higher percentage of nearer-term projected product sales being hedged than in successive periods.

As of March 31, 2021 and December 31, 2020, we had outstanding foreign currency forward contracts with aggregate notional amounts of $5.2 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 March 31, 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 three months ended March 31, 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 March 31,	
Derivatives in cash flow hedging relationships	**2021**	**2020**
Foreign currency contracts	$ 183	$ 239
Cross-currency swap contracts	(75)	(401)
Total unrealized gains (losses)	$ 108	$ (162)

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 both March 31, 2021 and December 31, 2020, we had interest rate swap contracts with aggregate notional amounts of $5.9 billion that hedge certain portions of our long-term debt issuances.

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

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

	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
Condensed Consolidated Balance Sheets locations	**March 31, 2021**	**December 31, 2020**	**March 31, 2021**	**December 31, 2020**
Current portion of long-term debt	$ 89	$ 89	$ 89	$ 89
Long-term debt	$ 6,085	$ 6,258	$ 302	$ 477

(1) Current portion of long-term debt includes $89 million of carrying value with discontinued hedging relationships as of both March 31, 2021 and December 31, 2020. Long-term debt includes $502 million and $525 million of carrying value with discontinued hedging relationships as of March 31, 2021 and December 31, 2020, respectively.

(2) Current portion of long-term debt includes $89 million of hedging adjustments on discontinued hedging relationships as of both March 31, 2021 and December 31, 2020. Long-term debt includes $402 million and $425 million of hedging adjustments on discontinued hedging relationships as of March 31, 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 March 31, 2021		
	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	$ 5,592	$ 13	$ (285)
The effects of cash flow and fair value hedging:			
Losses on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ (1)	$ —	$ —
Cross-currency swap contracts	$ —	$ (132)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ 175
Derivatives designated as hedging instruments	$ —	$ —	$ (152)

	Three months ended March 31, 2020		
	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	$ 5,894	$ 11	$ (346)
The effects of cash flow and fair value hedging:			
Gains (losses) on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency contracts	$ 49	$ —	$ —
Cross-currency swap contracts	$ —	$ (133)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ 210
Derivatives designated as hedging instruments	$ —	$ —	$ (190)

(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 where the corresponding hedged item was paid down in the period.

No portions of our cash flow hedge contracts were excluded from the assessment of hedge effectiveness. As of March 31, 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 March 31, 2021 and December 31, 2020, the total notional amounts of these foreign currency forward contracts were $0.8 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 months ended March 31, 2021 and 2020.

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

	Derivative assets		Derivative liabilities	
March 31, 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 assets	$ 79	Accrued liabilities/ Other noncurrent liabilities	$ 107
Cross-currency swap contracts	Other current assets/ Other assets	153	Accrued liabilities/ Other noncurrent liabilities	291
Interest rate swap contracts	Other current assets/ Other assets	33	Accrued liabilities/ Other noncurrent liabilities	134
Total derivatives designated as hedging instruments		$ 265		$ 532

	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 assets	$ 28	Accrued liabilities/ Other noncurrent liabilities	$ 237
Cross-currency swap contracts	Other current assets/ Other assets	255	Accrued liabilities/ Other noncurrent liabilities	318
Interest rate swap contracts	Other current assets/ Other 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 March 31, 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.

12. 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 in this footnote our legal proceedings and other matters that are significant or that we believe could become significant.

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, or 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 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, or 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 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

KYPROLIS® ANDA Patent Litigation

Onyx Therapeutics, Inc. v. Cipla Limited, et al.

On March 8, 2021, the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court) affirmed the May 2020 judgment of the U.S. District Court for the District of Delaware (the Delaware District Court), which judgment had found in favor of Onyx Therapeutics, Inc. (Onyx), and against Cipla Limited and Cipla USA, Inc. (collectively, Cipla), on infringement, validity and enforceability of claims 23 and 24 of Onyx's U.S. Patent No. 7,417,042 (the '042 Patent), claim 1 of U.S. Patent No. 8,207,125 (the '125 Patent), and claim 31 of U.S. Patent No. 7,737,112 (the '112 Patent). The May 2020 judgment also includes an injunction prohibiting Cipla from making, using, offering to sell, selling or importing into the United States Cipla's carfilzomib product during the term of the three asserted patents (the '042, '125 and '112 Patents). On April 7, 2021, Cipla filed a petition in the Federal Circuit Court requesting panel rehearing of the Federal Circuit Court's decision on Cipla's appeal, which was denied on April 23, 2021.

Otezla® ANDA Patent Litigation

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

On March 24, 2021, based on a joint request by Amgen and Prinston Pharmaceutical Inc. (Prinston), the U.S. District Court for the District of New Jersey (the New Jersey District Court) entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Prinston's apremilast product during the term of U.S. Patent Nos. 7,427,638 and 10,092,541, unless authorized pursuant to a confidential settlement agreement. On April 6, 2021, based on a joint request by Amgen together with Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. (collectively, Aurobindo), the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Aurobindo's apremilast product during the term of U.S. Patent Nos. 6,962,940; 7,208,516; 7,427,638; 7,659,302; 7,893,101; 8,455,536; 8,802,717; 9,018,243; 9,724,330; 9,872,854; and 10,092,541 unless authorized pursuant to a confidential settlement agreement.

Sensipar® (cinacalcet) ANDA Patent Litigation

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

On March 24, 2021, the Delaware District Court commenced an evidentiary hearing on the request by Piramal Healthcare UK Limited and Slate Run Pharmaceuticals LLC for damages caused by the injunction during the pendency of Amgen's appeal.

Repatha® Patent Litigation

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

On February 11, 2021, the Federal Circuit Court issued a decision affirming the Delaware District Court's ruling that claims 19 and 29 of our U.S. Patent No. 8,829,165 and claim 7 of our U.S. Patent No. 8,859,741 are invalid for failing to meet the enablement requirement. Amgen filed a petition for rehearing en banc on April 14, 2021. On April 15, 2021, the Federal Circuit Court invited Sanofi and Regeneron to respond to Amgen's petition. Sanofi and Regeneron's response is due May 28, 2021.

NEUPOGEN® (filgrastim)/Neulasta® Patent Litigation

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

On March 16, 2021, the Delaware District Court issued an order rescheduling the trial between Amgen Inc. and its wholly owned subsidiary, Amgen Manufacturing, Limited (collectively, Amgen) and Pfizer Inc. and Hospira Inc. (collectively, Pfizer) to begin on September 20, 2021.

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

On March 23, 2021, the Delaware District Court denied Pfizer's motion to dismiss the complaint by Amgen, which alleges Pfizer's infringement of U.S. Patent No. 8,273,707. On April 6, 2021, the Delaware District Court stayed further proceedings in the matter pending claim construction of the patent claims. A claim construction hearing is scheduled for June 11, 2021.

Patent Trial and Appeal Board (PTAB) Challenge

Lupin PTAB Challenge

On December 15, 2020, Lupin Limited filed a petition to institute inter parties review (IPR) proceeding at the U.S. Patent and Trademark Office (USPTO) of U.S. Patent No. 9,856,287 (the '287 Patent) challenging claims of the '287 Patent as unpatentable. Amgen's preliminary response was filed on April 14, 2021, and the PTAB has no more than three months to decide whether to institute a proceeding.

Antitrust Class Action

Sensipar® Antitrust Class Actions

On February 16, 2021, the plaintiffs in the antitrust class action lawsuit brought on behalf of putative classes of direct or indirect purchasers of Sensipar® filed their amended complaints. On March 4, 2021, a stipulation and order regarding the filing of a second amended complaint were filed to add another plaintiff: Teamsters Western Region & Local 177 Health Care Fund. On March 17, 2021, a defendant, MSP Recovery Claims, Series LLC, filed its notice of voluntary dismissal. On March 30, 2021, the remaining defendants, including Amgen, filed their motions to dismiss the second amended complaint.

Humira® Biosimilar Antitrust Class Actions

On February 25, 2021, oral argument was held by the U.S. Court of Appeals for the Seventh Circuit on the appeal by plaintiffs-appellants of the lower court's dismissal of the consolidated complaint with prejudice.

13. Subsequent event

On April 16, 2021, Amgen completed its acquisition of Five Prime Therapeutics, Inc. (Five Prime) for $38.00 per share in cash, for a total transaction price of approximately $1.9 billion. Five Prime is a clinical-stage biotechnology company focused on developing immuno-oncology and targeted cancer therapies. The transaction is expected to be accounted for as an asset acquisition and will be included in our condensed consolidated financial statements in the second quarter of 2021.

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. 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. 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®, Neulasta®, Otezla®, XGEVA®, 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), Parsabiv® (etelcalcetide), Aimovig® (erenumab-aooe), NEUPOGEN® and Sensipar®/Mimpara™.

COVID-19 pandemic

A novel strain of coronavirus (SARS-CoV-2, or severe acute respiratory syndrome coronavirus 2, causing coronavirus disease 19, or COVID-19) was declared a global pandemic by the World Health Organization (WHO) on March 11, 2020. Since the onset of the pandemic in 2020 and into 2021, we have been closely monitoring the pandemic's effects on our global operations. We have taken appropriate steps to minimize risks to our employees. A significant number of our employees have been working remotely, with the exception of certain staff that require access to our manufacturing and laboratory research facilities, in accordance with applicable government health and safety protocols and guidance issued in response to the COVID-19 pandemic. To date, our remote working arrangements have not significantly affected our ability to maintain critical business operations, and we have not experienced disruptions or shortages of our supply of medicines.

Since the beginning of the COVID-19 pandemic, we have seen changes in demand for some of our products, including lower demand for certain products as continuing patient access to those products has been affected by COVID-19, particularly in the early phases of the pandemic in 2020. For example, near the end of March 2020, we began to observe a decline in sales of Prolia®, as elderly patients, who are relatively more vulnerable to COVID-19, avoided doctors' offices. Demand has since recovered to varying degrees by product as local conditions improved, allowing patients to resume receiving their treatments. During the second half of 2020 and into 2021, we remain focused on assisting patients with their continuity of care and on increasing product access compared with what patients experienced during the earlier stages of the pandemic. Nevertheless, the cumulative missed patient visits and diagnoses since the start of the pandemic continue to impact our business, slowing diagnoses, treatment and new patient starts.

Since early 2021, global vaccination efforts have been underway to control the pandemic. However, uncertainty remains regarding the extent, availability and length of time to vaccinate a meaningful portion of the population as well as the degree of efficacy of such vaccination efforts on the trajectory of the pandemic. Challenges to vaccination efforts 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.

The majority of clinical trials that paused at the onset of the pandemic to ensure subject safety or data integrity have resumed. Study enrollment was affected negatively the most in the second quarter of 2020 and by the end of the year resumed to around pre-pandemic levels. We are continuously monitoring COVID-19 infection rates and working to mitigate such effects on future study enrollment. We continuously monitor our ability for study enrollment on an institution by institution basis and reevaluate the status of studies, pausing when uncertainty arises with regard to the trial sites' ability to ensure safety or data integrity. We remain focused on supporting our active clinical sites in providing care for these patients and in providing investigational drug supply. In addition, our organization is supporting efforts to combat the COVID-19 pandemic in a number of ways, including by (i) working to support production of therapeutic antibodies that could diminish the impact of COVID-19 on patients, (ii) joining a public–private partnership between leading companies in our industry and U.S. government health agencies to develop a strategy for a coordinated research response and (iii) investigating Otezla® as a potential immunomodulatory treatment in adult patients hospitalized with severe COVID-19 infections.

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 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.

Significant developments

Following is a summary of selected significant developments affecting our business that occurred since the filing of our Annual Report on Form 10-K for the year ended December 31, 2020. For additional developments or for a more comprehensive discussion of certain developments discussed below, see our Annual Report on Form 10-K for the year ended December 31, 2020.

Acquisition

Five Prime

- On April 16, 2021, Amgen completed its acquisition of Five Prime, a clinical-stage biotechnology company focused on developing immuno-oncology and targeted cancer therapies, for approximately $1.9 billion in cash.
- In April 2021, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for bemarituzumab as first-line treatment of patients with fibroblast growth factor receptor 2b (FGFR2b) overexpressing and human epidermal growth factor receptor 2 (HER2)-negative metastatic and locally advanced gastric and gastroesophageal adenocarcinoma in combination with fluoropyrimidine, leucovorin and oxaliplatin based on an FDA-approved companion diagnostic assay showing at least 10% of tumor cells overexpressing FGFR2b.

Products/Pipeline

Inflammation

Otezla®

- In February 2021, we announced the submission of a supplemental New Drug Application to the FDA for Otezla® for the treatment of adults with mild-to-moderate plaque psoriasis who are candidates for phototherapy or systemic therapy.

Oncology/Hematology

LUMAKRAS™ (sotorasib)*

- In February 2021, we announced that the FDA has granted Priority Review for LUMAKRAS™ for the treatment of patients with Kirsten rat sarcoma viral oncogene homolog (KRAS) G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), following at least one prior systemic therapy. Based on the Priority Review designation, the Prescription Drug User Fee Action (PDUFA) date for LUMAKRAS™ is August 16, 2021.

* FDA provisionally approved trade name

Selected financial information

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

	Three months ended March 31,		
	2021	2020	Change
Product sales			
U.S.	$ 3,903	$ 4,279	(9)%
ROW	1,689	1,615	5 %
Total product sales	5,592	5,894	(5)%
Other revenues	309	267	16 %
Total revenues	$ 5,901	$ 6,161	(4)%
Operating expenses	$ 3,772	$ 3,806	(1)%
Operating income	$ 2,129	$ 2,355	(10)%
Net income	$ 1,646	$ 1,825	(10)%
Diluted EPS	$ 2.83	$ 3.07	(8)%
Diluted shares	581	594	(2)%

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

Total product sales decreased for the three months ended March 31, 2021, primarily driven by declines in net selling prices for certain products, partially offset by unit demand increases from certain brands, including MVASI®, KANJINTI®, Repatha® and Prolia®. These results reflect the cumulative, continuing negative effect of COVID-19 on patient visits and new patient diagnoses. In addition, in the first quarter of 2021, ENBREL, Otezla® and Aimovig® followed the historic pattern of lower first quarter sales relative to the remainder of the year due to the impact of benefit plan changes, insurance reverifications and increased co-pay expenses as U.S. patients work through deductibles.

During the initial stages of the COVID-19 pandemic in early 2020, we experienced changes in demand for some of our products. The pandemic interrupted many physician–patient interactions, which led to delays in diagnosis and treatment, with varying degrees of impact across our portfolio. In general, sales of negatively affected products fell the most in the early part of the second quarter of 2020, with product demand beginning to show some recovery in the second half of 2020. In the first quarter of the current year, we continued to see some effect on demand as compared to pre-pandemic levels, including new patient prescriptions. Given the unpredictable nature of the pandemic, we expect that there could be ongoing intermittent disruptions in physician–patient interactions and, as a result, we continue to expect quarter-to-quarter variability. 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.

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, with the corresponding growth in Medicaid enrollees and uninsured individuals having a negative impact on product demand and sales. Overall, uncertainty remains around the timing and magnitude of our sales during the COVID-19 pandemic.

Other revenues increased for the three months ended March 31, 2021, primarily driven by higher royalties.

Operating expenses decreased slightly for the three months ended March 31, 2021, primarily driven by lower amortization expense from acquisition-related assets. Our operating expenses are expected to be higher in the remaining quarters of the year as we continue to invest in innovation and long-term growth. Additionally, we expect a charge in the second quarter to R&D expense as a result of the acquisition of Five Prime.

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 months ended March 31, 2021 and 2020.

Results of operations

Product sales

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

	Three months ended March 31,		
	2021	2020	Change
ENBREL	$ 924	$ 1,153	(20)%
Prolia®	758	654	16 %
Neulasta®	482	609	(21)%
Otezla®	476	479	(1)%
XGEVA®	468	481	(3)%
Aranesp®	355	422	(16)%
Repatha®	286	229	25 %
KYPROLIS®	251	280	(10)%
Other products	1,592	1,587	— %
Total product sales	$ 5,592	$ 5,894	(5)%

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.

ENBREL

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

	Three months ended March 31,		
	2021	2020	Change
ENBREL — U.S.	$ 894	$ 1,117	(20)%
ENBREL — Canada	30	36	(17)%
Total ENBREL	$ 924	$ 1,153	(20)%

The decrease in ENBREL sales for the three months ended March 31, 2021, was driven by favorable changes to estimated sales deductions in the prior year, lower unit demand and lower net selling price. For the remainder of 2021, we expect the trend of volume and net selling price declines to continue as compared to the prior year.

We are involved in patent litigation with the two companies seeking to market their FDA-approved biosimilar versions of ENBREL. See Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020. 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 March 31,		
	2021	2020	Change
Prolia® — U.S.	$ 501	$ 422	19 %
Prolia® — ROW	257	232	11 %
Total Prolia®	$ 758	$ 654	16 %

The increase in global Prolia® sales for the three months ended March 31, 2021, was primarily driven by higher unit demand. While disruptions from the effects of the COVID-19 pandemic to new and repeat patient visits have decreased, we anticipate that such disruptions will continue to affect demand in 2021, although to a lesser degree than that experienced in 2020. However, we expect further recovery in demand from these effects of COVID-19 going forward.

Neulasta®

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

	Three months ended March 31,		
	2021	2020	Change
Neulasta® — U.S.	$ 421	$ 534	(21)%
Neulasta® — ROW	61	75	(19)%
Total Neulasta®	$ 482	$ 609	(21)%

The decrease in global Neulasta® sales for the three months ended March 31, 2021, was primarily 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. We also expect other biosimilar versions to be approved in the future. For a discussion of ongoing patent litigations related to these and other biosimilars, see Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020, and Note 12, Contingencies and commitments, to the condensed consolidated financial statements.

Otezla®

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

	Three months ended March 31,		
	2021	2020	Change
Otezla® — U.S.	$ 366	$ 377	(3)%
Otezla® — ROW	110	102	8 %
Total Otezla®	$ 476	$ 479	(1)%

Global Otezla® sales for the three months ended March 31, 2021, slightly decreased as declines in net selling price and unfavorable changes in inventory were substantially offset by higher unit demand. While total prescription volume has increased, new to brand prescriptions were flat as COVID-19 continues to suppress the diagnosis and treatment of psoriasis patients.

For a discussion of ongoing 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, and Note 12, Contingencies and commitments, to the condensed consolidated financial statements.

XGEVA®

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

	Three months ended March 31,		
	2021	2020	Change
XGEVA® — U.S.	$ 334	$ 355	(6)%
XGEVA® — ROW	134	126	6 %
Total XGEVA®	$ 468	$ 481	(3)%

The decrease in U.S. XGEVA® sales for the three months ended March 31, 2021, was driven by lower unit demand from the impact of COVID-19. The increase in ROW XGEVA® sales for the same period was driven by higher unit demand in Asia, offset by lower net selling price in that region.

Aranesp®

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

	Three months ended March 31,		
	2021	2020	Change
Aranesp® — U.S.	$ 125	$ 175	(29)%
Aranesp® — ROW	230	247	(7)%
Total Aranesp®	$ 355	$ 422	(16)%

The decrease in global Aranesp® sales for the three months ended March 31, 2021, was driven by declines in unit demand and net selling price due to competition.

Aranesp® faces competition from a long-acting erythropoiesis-stimulating agent (ESA). Aranesp® also faces competition from a biosimilar version of EPOGEN®. For the remainder of 2021, we expect that sales will continue to decline compared to the prior year due to short- and long-acting competition.

KYPROLIS®

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

	Three months ended March 31,		
	2021	2020	Change
KYPROLIS® — U.S.	$ 159	$ 187	(15)%
KYPROLIS® — ROW	92	93	(1)%
Total KYPROLIS®	$ 251	$ 280	(10)%

The decrease in global KYPROLIS® sales for the three months ended March 31, 2021, was driven by lower unit demand primarily a result of slower growth in the multiple myeloma segment as fewer patients were diagnosed and treated due to COVID-19.

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 Note 12, Contingencies and commitments, to the condensed consolidated financial statements. 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.

Repatha®

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

	Three months ended March 31,		
	2021	2020	Change
Repatha® — U.S.	$ 139	$ 124	12 %
Repatha® — ROW	147	105	40 %
Total Repatha®	$ 286	$ 229	25 %

The increase in global Repatha® sales for the three months ended March 31, 2021, was driven by higher unit demand, partially offset by lower net selling price and favorable changes to estimated sales deductions in the prior year.

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, and Note 12, Contingencies and commitments, to the condensed consolidated financial statements.

Other products

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

	Three months ended March 31,		
	2021	2020	Change
Nplate® — U.S.	$ 112	$ 127	(12)%
Nplate® — ROW	115	91	26 %
Vectibix® — U.S.	79	80	(1)%
Vectibix®— ROW	112	122	(8)%
Parsabiv® — U.S.	46	146	(68)%
Parsabiv® — ROW	33	29	14 %
MVASI® — U.S.	224	108	*
MVASI® — ROW	70	7	*
EPOGEN® — U.S.	125	155	(19)%
KANJINTI® — U.S.	130	96	35 %
KANJINTI® — ROW	31	23	35 %
BLINCYTO® — U.S.	65	57	14 %
BLINCYTO® — ROW	42	37	14 %
Aimovig® — U.S.	66	71	(7)%
EVENITY® — U.S.	57	37	54 %
EVENITY®— ROW	50	63	(21)%
Sensipar® — U.S.	—	42	(100)%
Sensipar®/Mimpara™ — ROW	23	81	(72)%
AMGEVITA™ — ROW	106	86	23 %
NEUPOGEN® — U.S.	18	45	(60)%
NEUPOGEN® — ROW	16	20	(20)%
Other — U.S.	42	24	75 %
Other — ROW	30	40	(25)%
Total other products	$ 1,592	$ 1,587	— %
Total U.S. — other products	$ 964	$ 988	(2)%
Total ROW — other products	628	599	5 %
Total other products	$ 1,592	$ 1,587	— %

* Change in excess of 100%.

Operating expenses

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

	Three months ended March 31,		
	2021	2020	Change
Operating expenses:			
Cost of sales	$ 1,490	$ 1,513	(2)%
% of product sales	26.6 %	25.7 %	
% of total revenues	25.2 %	24.6 %	
Research and development	$ 967	$ 952	2 %
% of product sales	17.3 %	16.2 %	
% of total revenues	16.4 %	15.5 %	
Selling, general and administrative	$ 1,254	$ 1,316	(5)%
% of product sales	22.4 %	22.3 %	
% of total revenues	21.3 %	21.4 %	
Other	$ 61	$ 25	*

* Change in excess of 100%.

Cost of sales

Cost of sales increased to 25.2% of total revenues for the three months ended March 31, 2021, driven by unfavorable product mix and higher profit share and royalty expenses, partially offset by lower amortization expense from acquisition-related assets.

Research and development

The increase in R&D expense for the three months ended March 31, 2021, was primarily driven by higher research and early pipeline spend, including a recent business development acquisition, partially offset by lower late-stage program support.

Selling, general and administrative

The decrease in Selling, general and administrative expense for the three months ended March 31, 2021, was driven by lower spend in general and administrative activities as well as favorable adjustments to estimated U.S. healthcare reform federal excise fees.

Other

Other operating expenses for the three months ended March 31, 2021, consisted primarily of expenses related to cost savings initiatives. Other operating expenses for the three months ended March 31, 2020, consisted of an impairment charge for an early-stage program.

Nonoperating expense/income and income taxes

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

	Three months ended March 31,	
	2021	2020
Interest expense, net	$ (285)	$ (346)
Other income, net	$ 13	$ 11
Provision for income taxes	$ 211	$ 195
Effective tax rate	11.4 %	9.7 %

Interest expense, net

The decrease in Interest expense, net, for the three months ended March 31, 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, partially offset by higher overall debt outstanding in the current year period.

Other income, net

The increase in Other income, net, for the three months ended March 31, 2021, was primarily due to gains recognized on our investments in limited partnerships in the current year, offset by losses incurred in connection with our BeiGene investment, gains on sales of interest-bearing securities in prior periods and a decline in interest income in the current year.

Income taxes

The increase in our effective tax rate for the three months ended March 31, 2021, was primarily due to changes in the jurisdictional mix of earnings.

The new 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. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 became effective which provides additional economic stimulus to address the impact of the COVID-19 pandemic. We do not expect any significant tax benefit from this Act. We continue to monitor for tax legislative developments.

As previously disclosed, 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 disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. However, we have been unable to reach resolution at the administrative appeals level. We anticipate that we will receive a Notice of Deficiency which we will vigorously contest 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 are pursuing resolution with the IRS administrative appeals office. 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 consolidated financial statements

See Note 3, 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):

	March 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 10,566	$ 10,647
Total assets	$ 62,539	$ 62,948
Current portion of long-term debt	$ 1,556	$ 91
Long-term debt	$ 31,129	$ 32,895
Stockholders' equity	$ 9,334	$ 9,409

Cash, cash equivalents and marketable securities

Our balance of cash, cash equivalents and marketable securities was $10.6 billion at March 31, 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 primarily 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 in a strategic manner 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 December 2020, the Board of Directors declared a quarterly cash dividend of $1.76 per share of common stock for the first quarter of 2021, an increase of 10% for this period, which was paid on March 8, 2021. In March 2021, the Board of Directors declared a quarterly cash dividend of $1.76 per share of common stock, which will be paid on June 8, 2021.

We have also returned capital to stockholders through our stock repurchase program. During the three months ended March 31, 2021, we executed trades to repurchase $865 million of common stock. As of March 31, 2021, $5.5 billion of authorization remained available under our stock repurchase program.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of March 31, 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, capital expenditure and debt service requirements, our plans to pay dividends and repurchase stock and 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 March 31, 2021.

Cash flows

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

	Three months ended March 31,	
	2021	2020
Net cash provided by operating activities	$ 2,104	$ 2,134
Net cash used in investing activities	$ (319)	$ (230)
Net cash used in financing activities	$ (1,939)	$ (254)

Operating

Cash provided by operating activities is expected to be our primary recurring source of funds. Cash provided by operating activities during the three months ended March 31, 2021, decreased compared with the same period in the prior year primarily due to the prior year monetization of interest rate swap contracts, the timing of payments for sales deductions and lower current year net income, net of noncash items, substantially offset by increased collections from customers as a result of the impact in the prior year from of the Otezla® acquisition.

Investing

Cash used in investing activities during the three months ended March 31, 2021, was primarily due to net cash outflows related to capital expenditures of $166 million and net activity related to marketable securities of $74 million. Cash used in investing activities during the three months ended March 31, 2020, was primarily due to our $2.6 billion equity investment in BeiGene and capital expenditures of $142 million, substantially offset by net cash inflows related to marketable securities of $2.6 billion. We currently estimate 2021 spending on capital projects to be approximately $900 million.

Financing

Cash used in financing activities during the three months ended March 31, 2021, was primarily due to the payment of dividends of $1.0 billion and payments to repurchase our common stock of $871 million. Cash used in financing activities during the three months ended March 31, 2020, was primarily due to repayment of debt of $3.3 billion, payments to repurchase our common stock of $1.0 billion and payment of dividends of $945 million, offset by net proceeds from the issuance of debt of $5.0 billion. See Note 8, Financing arrangements, and Note 9, 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. There have been no material changes during the three months ended March 31, 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.

Item 4. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under the Securities Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to facilitate timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and, in reaching a reasonable level of assurance, Amgen's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2021.

Management determined that, as of March 31, 2021, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

See Note 12, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the period ended March 31, 2021, 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 involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Below, we are providing, in supplemental form, the material changes to our risk factors that occurred during the past quarter. Our risk factors disclosed in Part I, Item 1A, of our Annual Report, on Form 10-K for the year ended December 31, 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 shut-downs 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. 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. 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 even if conditions begin to improve. There has been a resurgence in COVID-19 infections in numerous jurisdictions in the fourth quarter of 2020 and first quarter of 2021, resulting in the reinstatement of stricter restrictions and shutdowns in a number of jurisdictions, including in the U.S. and EU 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, 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 current and/or future variants of the virus. 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 U.S., 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 one of Lilly's COVID-19 antibody therapies) 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 used in the manufacturing, distribution, or administration of our products. In addition, unpredictable increases in demand for certain of our products could exceed our capacity to meet such demand, which could adversely affect our financial results and customer relationships.

The COVID-19 pandemic and the volatile global economic conditions stemming from it may precipitate or amplify the other risks described in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 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 shut-down 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.

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 could 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 could 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 price directly, limit drug reimbursement based on prices abroad or permit importation of drugs from Canada. 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 that activity continues today. 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. We expect H.R. 3 to again be debated by Congress in the coming months. Most recently, Congress passed the American Rescue Plan Act of 2021 to provide additional stimulus money and support for COVID relief. As part of that legislation, a provision that is expected to be implemented in 2024 was included that has the effect of increasing the Medicaid rebate liability for some medicines that increase prices in excess of inflation. 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 Organization for Economic Co-operation and Development (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. On April 26, the court ordered that the case remain

stayed and directed the parties to file a joint status report by July 26, 2021. 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. Notwithstanding these stays, 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, including proposals similar to the MFN rule, for the foreseeable future.

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 Centers for Medicare & Medicaid Services (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 such 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, it also is unclear how the current Administration views this rule and how plans and PBMs may respond when it goes into effect. 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, and patients are facing additional access challenges due to dialysis organization restrictions on Parsabiv® utilization in favor of generic cinacalcet. 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, but the start date of such programs has been pushed back to 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 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. We disagree with the proposed adjustments and calculations and have been pursuing resolution with the IRS administrative appeals office. However, we have been unable to reach resolution at the administrative appeals level. We anticipate that we will receive a Notice of Deficiency for 2010, 2011 and 2012, which we will vigorously contest 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 2013, 2014 and 2015 proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. 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 new 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. Changes to existing tax law in the U.S., the U.S. territory of Puerto Rico, or other jurisdictions, including efforts by the OECD to align countries on corporate tax matters 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 March 31, 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]
January 1 - 31	696,324	$ 241.03	696,324	$ 2,808,745,008
February 1 - 28	1,328,370	$ 234.22	1,328,370	$ 2,497,613,302
March 1 - 31	1,628,459	$ 237.23	1,628,459	$ 5,511,289,116
Total	3,653,153	$ 236.86	3,653,153	

[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.

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.)
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 (As Amended and Restated effective January 1, 2020). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.22+	Agreement between Amgen Inc. and Murdo Gordon, dated July 25, 2018. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2018 on October 31, 2018 and incorporated herein by reference.)
10.23+	Agreement between Amgen Inc. and Peter Griffith, dated October 18, 2019. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)
10.24	Second Amended and Restated Credit Agreement, dated December 12, 2019, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent. (Filed as an exhibit to Form 8-K on December 12, 2019 and incorporated herein by reference.)
10.25	Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)
10.26	Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.27	Letter Agreement, dated June 25, 2019, by and between Amgen Inc. and UCB Celltech (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2019 on July 31, 2019 and incorporated herein by reference.)
10.28	Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)
10.29	Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.30	Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.31	Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)

10.32	Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.33	Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
10.34	Side Letter Regarding Collaboration Agreement and Stivarga Agreement, dated February 13, 2020, by and between Onyx Pharmaceuticals, Inc. and Bayer HealthCare LLC. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)
10.35	Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.36	Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.37	Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.38	Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.39	Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.40	Amendment No. 1 to the Collaboration Agreement, dated March 20, 2018, by and between Novartis Pharma AG and Amgen Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.)
10.41	Amendment No. 2 to the Collaboration Agreement, dated August 19, 2020, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2020 on October 29, 2020 and incorporated herein by reference.)
10.42	Collaboration Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene Switzerland GmbH, a wholly-owned subsidiary of BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.43	Guarantee, dated as of October 31, 2019, made by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.44	Share Purchase Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.45	Amendment No. 1 to Share Purchase Agreement, dated December 6, 2019, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.46	Restated Amendment No. 2 to Share Purchase Agreement, dated September 24, 2020, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2020 on October 29, 2020 and incorporated herein by reference.)

10.47	Collaboration Agreement dated March 30, 2012 by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, a wholly owned subsidiary of AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2012 on May 8, 2012 and incorporated herein by reference.)
10.48	Amendment No. 1 to the Collaboration Agreement, dated October 1, 2014, by and among Amgen Inc., AstraZeneca Collaboration Ventures, LLC and AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2014 on February 19, 2015 and incorporated herein by reference.)
10.49	Amendment Nos. 2 through 6 to the March 30, 2012 Collaboration Agreement between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, dated May 2 and 27 and October 2, 2016, January 31, 2018, and May 15, 2020, respectively (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2020 on July 29, 2020 and incorporated herein by reference.)
10.50	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.)
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: April 27, 2021

By: /s/ PETER H. GRIFFITH

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

CERTIFICATIONS

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

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

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

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

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

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

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

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

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

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

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

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

Date: April 27, 2021

/s/ ROBERT A. BRADWAY

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

CERTIFICATIONS

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

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

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

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

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

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

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

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

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

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

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

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

Date: April 27, 2021

/s/ PETER H. GRIFFITH

Peter H. Griffith
Executive Vice President and Chief Financial Officer

Exhibit 32

Certification of Chief Executive Officer

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: April 27, 2021

/s/ ROBERT A. BRADWAY

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

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

Certification of Chief Financial Officer

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: April 27, 2021

/s/ PETER H. GRIFFITH

Peter H. Griffith
Executive Vice President and Chief Financial Officer

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