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

(Mark One)

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

For the quarterly period ended September 30, 2023

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**
2.00% Senior Notes due 2026	**AMGN26**	**The Nasdaq Stock Market LLC**

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

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

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

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

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

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

Yes ☐ No ☑

As of October 26, 2023, the registrant had 535,178,027 shares of common stock, $0.0001 par value, outstanding.

AMGEN INC.

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Defined Terms and Products

Defined terms

We use several terms in this Form 10-Q, including but not limited to those that are finance, regulation and disease-state related as well as names of other companies, which are given below.

Term	Description
AOCI	accumulated other comprehensive income (loss)
ASR	accelerated share repurchase
BeiGene	BeiGene, Ltd.
Bergamo	Laboratorio Quimico Farmaceutico Bergamo Ltda
ChemoCentryx	ChemoCentryx, Inc.
CMS	Centers for Medicare & Medicaid Services
COVID-19	coronavirus disease 2019
Eczacıbaşı	EIS Eczacıbaşı İlaç, Sınai ve Finansal Yatırımlar Sanayi ve Ticaret A.Ş.
EMA	European Medicines Agency
EPS	earnings per share
ESG	environmental, social and governance
EU	European Union
FDA	U.S. Food and Drug Administration
Fitch	Fitch Ratings, Inc.
FTC	Federal Trade Commission
GAAP	U.S. generally accepted accounting principles
Gensenta	Gensenta İlaç Sanayi ve Ticaret A.Ş.
HHS	U.S. Department of Health and Human Services
Horizon	Horizon Therapeutics plc
IPR&D	in-process research and development
IRA	Inflation Reduction Act of 2022
IRS	Internal Revenue Service
ISDA	International Swaps and Derivatives Association, Inc.
LIBOR	London Interbank Offered Rate
MD&A	management’s discussion and analysis
Moody’s	Moody’s Investors Service, Inc.
Neumora	Neumora Therapeutics, Inc.
OECD	Organisation for Economic Co-operation and Development
PBM	pharmacy benefit manager
R&D	research and development
RAR	Revenue Agent Report
ROW	rest of world
S&P	Standard & Poor’s Financial Services LLC
SEC	U.S. Securities and Exchange Commission
SG&A	selling, general and administrative
SOFR	Secured Overnight Financing Rate
Teneobio	Teneobio, Inc.
U.S. Treasury	U.S. Department of Treasury
UTB	unrecognized tax benefit

Products

The brand names of our products, our delivery devices and certain of our product candidates and their associated generic names are given below.

Term	Description
Aimovig	Aimovig® (erenumab-aooe)
AMJEVITA/AMGEVITA	AMJEVITA® (adalimumab-atto)/AMGEVITA™ (adalimumab)
Aranesp	Aranesp® (darbepoetin alfa)
AVSOLA	AVSOLA® (infliximab-axxq)
BEKEMV	BEKEMV™ (eculizumab)
BLINCYTO	BLINCYTO® (blinatumomab)
Corlanor	Corlanor® (ivabradine)
ENBREL	Enbrel® (etanercept)
EPOGEN	EPOGEN® (epoetin alfa)
EVENITY	EVENITY® (romosozumab-aqqg)
IMLYGIC	IMLYGIC® (talimogene laherparepvec)
KANJINTI	KANJINTI® (trastuzumab-anns)
KYPROLIS	KYPROLIS® (carfilzomib)
LUMAKRAS/LUMYKRAS	LUMAKRAS®/LUMYKRAS™ (sotorasib)
MVASI	MVASI® (bevacizumab-awwb)
Neulasta	Neulasta® (pegfilgrastim)
NEUPOGEN	NEUPOGEN® (filgrastim)
Nplate	Nplate® (romiplostim)
Otezla	Otezla® (apremilast)
Parsabiv	Parsabiv® (etelcalcetide)
Prolia	Prolia® (denosumab)
Repatha	Repatha® (evolocumab)
RIABNI	RIABNI® (rituximab-arrx)
Sensipar/Mimpara	Sensipar®/Mimpara™ (cinacalcet)
TAVNEOS	TAVNEOS® (avacopan)
TEZSPIRE	TEZSPIRE® (tezepelumab-ekko)
Vectibix	Vectibix® (panitumumab)
XGEVA	XGEVA® (denosumab)

Item 1. FINANCIAL STATEMENTS

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenues:				
Product sales	$ 6,548	$ 6,237	$ 19,077	$ 18,249
Other revenues	355	415	917	1,235
Total revenues	6,903	6,652	19,994	19,484
Operating expenses:				
Cost of sales	1,806	1,588	5,339	4,659
Research and development	1,079	1,112	3,250	3,110
Selling, general and administrative	1,353	1,287	3,905	3,842
Other	644	5	874	537
Total operating expenses	4,882	3,992	13,368	12,148
Operating income	2,021	2,660	6,626	7,336
Other income (expense):				
Interest expense, net	(759)	(368)	(2,054)	(991)
Other income (expense), net	685	100	2,431	(747)
Income before income taxes	1,947	2,392	7,003	5,598
Provision for income taxes	217	249	1,053	662
Net income	$ 1,730	$ 2,143	$ 5,950	$ 4,936
Earnings per share:				
Basic	$ 3.23	$ 4.01	$ 11.12	$ 9.16
Diluted	$ 3.22	$ 3.98	$ 11.06	$ 9.11
Shares used in calculation of earnings per share:				
Basic	535	535	535	539
Diluted	538	538	538	542

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Net income	$ 1,730	$ 2,143	$ 5,950	$ 4,936
Other comprehensive income, net of reclassification adjustments and taxes:				
Foreign currency translation	(44)	(109)	(5)	(225)
Cash flow hedges	181	138	73	378
Other	17	(9)	37	(9)
Other comprehensive income, net of reclassification adjustments and taxes	154	20	105	144
Comprehensive income	$ 1,884	$ 2,163	$ 6,055	$ 5,080

See accompanying notes.

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

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,741	$ 7,629
Marketable securities	—	1,676
Trade receivables, net	6,145	5,563
Inventories	5,026	4,930
Other current assets	2,565	2,388
Total current assets	48,477	22,186
Property, plant and equipment, net	5,563	5,427
Intangible assets, net	13,150	16,080
Goodwill	15,509	15,529
Other noncurrent assets	7,835	5,899
Total assets	$ 90,534	$ 65,121
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,358	$ 1,572
Accrued liabilities	14,168	12,524
Current portion of long-term debt	1,428	1,591
Total current liabilities	16,954	15,687
Long-term debt	59,040	37,354
Long-term tax liabilities	4,579	5,757
Other noncurrent liabilities	2,305	2,662
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding—535.1 shares in 2023 and 534.0 shares in 2022	32,753	32,514
Accumulated deficit	(24,971)	(28,622)
Accumulated other comprehensive loss	(126)	(231)
Total stockholders' equity	7,656	3,661
Total liabilities and stockholders' equity	$ 90,534	$ 65,121

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, 2022	534.0	$ 32,514	$ (28,622)	$ (231)	$ 3,661
Net income	—	—	2,841	—	2,841
Other comprehensive loss, net of taxes	—	—	—	(37)	(37)
Dividends declared on common stock ($2.13 per share)	—	—	(1,138)	—	(1,138)
Issuance of common stock in connection with the Company's equity award programs	0.3	11	—	—	11
Stock-based compensation expense	—	47	—	—	47
Tax impact related to employee stock-based compensation expense	—	(37)	—	—	(37)
Balance as of March 31, 2023	534.3	32,535	(26,919)	(268)	5,348
Net income	—	—	1,379	—	1,379
Other comprehensive loss, net of taxes	—	—	—	(12)	(12)
Issuance of common stock in connection with the Company's equity award programs	0.6	16	—	—	16
Stock-based compensation expense	—	119	—	—	119
Tax impact related to employee stock-based compensation expense	—	(69)	—	—	(69)
Balance as of June 30, 2023	534.9	32,601	(25,540)	(280)	6,781
Net income	—	—	1,730	—	1,730
Other comprehensive income, net of taxes	—	—	—	154	154
Dividends declared on common stock ($2.13 per share)	—	—	(1,161)	—	(1,161)
Issuance of common stock in connection with the Company's equity award programs	0.2	33	—	—	33
Stock-based compensation expense	—	124	—	—	124
Tax impact related to employee stock-based compensation expense	—	(5)	—	—	(5)
Balance as of September 30, 2023	535.1	$ 32,753	$ (24,971)	$ (126)	$ 7,656

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

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of December 31, 2021	558.3	$ 32,096	$ (24,600)	$ (796)	$ 6,700
Net income	—	—	1,476	—	1,476
Other comprehensive income, net of taxes	—	—	—	33	33
Dividends declared on common stock ($1.94 per share)	—	—	(1,034)	—	(1,034)
Issuance of common stock in connection with the Company's equity award programs	0.5	18	—	—	18
Stock-based compensation expense	—	78	—	—	78
Tax impact related to employee stock-based compensation expense	—	(45)	—	—	(45)
Repurchases of common stock	(24.6)	(900)	(5,410)	—	(6,310)
Balance as of March 31, 2022	534.2	31,247	(29,568)	(763)	916
Net income	—	—	1,317	—	1,317
Other comprehensive income, net of taxes	—	—	—	91	91
Issuance of common stock in connection with the Company's equity award programs	0.7	45	—	—	45
Stock-based compensation expense	—	120	—	—	120
Tax impact related to employee stock-based compensation expense	—	(69)	—	—	(69)
Other	—	—	(1)	—	(1)
Balance as of June 30, 2022	534.9	31,343	(28,252)	(672)	2,419
Net income	—	—	2,143	—	2,143
Other comprehensive income, net of taxes	—	—	—	20	20
Dividends declared on common stock ($1.94 per share)	—	—	(1,057)	—	(1,057)
Issuance of common stock in connection with the Company's equity award programs	0.1	15	—	—	15
Stock-based compensation expense	—	121	—	—	121
Tax impact related to employee stock-based compensation expense	—	(8)	—	—	(8)
Repurchases of common stock	(1.5)	900	(900)	—	—
Balance as of September 30, 2022	533.5	$ 32,371	$ (28,066)	$ (652)	$ 3,653

See accompanying notes.

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

	Nine months ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net income	$ 5,950	$ 4,936
Depreciation, amortization and other	2,691	2,506
Deferred income taxes	(650)	(847)
Adjustments for equity method investments	(17)	713
Loss on divestiture	—	565
(Gains) losses on equity securities	(1,304)	113
Other items, net	849	123
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	(582)	(566)
Inventories	(82)	(651)
Other assets	(332)	166
Accounts payable	(215)	(142)
Accrued income taxes, net	998	(492)
Long-term tax liabilities	293	185
Other liabilities	334	463
Net cash provided by operating activities	7,933	7,072
Cash flows from investing activities:		
Purchases of marketable securities	(1)	(2,363)
Proceeds from sales of marketable securities	1,125	—
Proceeds from maturities of marketable securities	550	447
Purchases of property, plant and equipment	(863)	(596)
Other	74	(59)
Net cash provided by (used in) investing activities	885	(2,571)
Cash flows from financing activities:		
Net proceeds from issuance of debt	23,781	6,938
Extinguishment of debt	(550)	(297)
Repayment of debt	(1,454)	—
Repurchases of common stock	—	(6,360)
Dividends paid	(3,416)	(3,156)
Other	(67)	(113)
Net cash provided by (used in) financing activities	18,294	(2,988)
Increase in cash and cash equivalents	27,112	1,513
Cash and cash equivalents at beginning of period	7,629	7,989
Cash and cash equivalents at end of period	$ 34,741	$ 9,502

See accompanying notes.

1. Summary of significant accounting policies

Business

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

Basis of presentation

The financial information for the three and nine months ended September 30, 2023 and 2022, 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, 2022, and with our condensed consolidated financial statements and the notes thereto contained in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2023 and June 30, 2023.

Principles of consolidation

The condensed consolidated financial statements include the accounts of Amgen as well as its majority-owned subsidiaries. In determining whether we are the primary beneficiary of a variable interest entity, we consider whether we have both the power to direct activities of the entity that most significantly impact the entity's economic performance and the obligation to absorb losses of or the right to receive benefits from the entity that could potentially be significant to that entity. We do not have any significant interests in any variable interest entities of which we are the primary beneficiary. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of condensed consolidated financial statements in conformity with 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 $9.7 billion and $9.3 billion as of September 30, 2023 and December 31, 2022, respectively.

Recent accounting pronouncements

No new accounting pronouncements were issued or adopted for the nine months ended September 30, 2023, that materially impacted the Company.

2. Restructuring

In the first quarter of 2023, we initiated a restructuring plan to enhance continued innovation, including investments in first-in-class medicines, while improving our cost structure. As part of the plan, we are reallocating resources to the areas of the business that will enable long-term growth.

We now expect that we will incur $250 million to $350 million of pretax charges in 2023 in connection with our restructuring plan, including (i) separation and other headcount-related costs with respect to staff reductions and (ii) asset-related charges that consist primarily of asset impairments and other related costs resulting from rationalization of our geographic footprint.

The following tables summarize recorded charges related to the restructuring plan by type of activity and the locations recognized within the Condensed Consolidated Statements of Income (in millions):

	Three months ended September 30, 2023		
	Separation costs	Asset impairments and other charges	Total
Cost of sales	$ —	$ 1	$ 1
Research and development	—	—	—
Selling, general and administrative	—	13	13
Other	16	1	17
Total	$ 16	$ 15	$ 31

	Nine months ended September 30, 2023		
	Separation costs	Asset impairments and other charges	Total
Cost of sales	$ —	$ 36	$ 36
Research and development	—	17	17
Selling, general and administrative	—	13	13
Other	182	4	186
Total	$ 182	$ 70	$ 252

As of September 30, 2023, total restructuring liability decreased to $54 million primarily due to payments related to separation costs. The total restructuring liability was included in Accrued liabilities in the Condensed Consolidated Balance Sheets.

3. Acquisitions and divestitures

Acquisition of Horizon Therapeutics plc

On October 6, 2023, Amgen completed its acquisition of Horizon for $116.50 per share in cash, representing a transaction equity value of approximately $27.8 billion. Horizon is a global biotechnology company focused on the discovery, development and commercialization of medicines that address critical needs of patients impacted by rare, autoimmune and severe inflammatory diseases. The acquisition aligns with Amgen's core strategy of delivering innovative medicines that make a significant difference for patients suffering from serious diseases and strengthens Amgen's leading inflammation portfolio by adding first-in-class, early-in-lifecycle medicines such as TEPEZZA® (teprotumumab-trbw), KRYSTEXXA® (pegloticase) and UPLIZNA® (inebilizumab-cdon), which treat rare inflammatory diseases.

The accounting impact of this acquisition and the results of operations for Horizon will be included in our consolidated financial statements beginning in the fourth quarter of 2023. The initial accounting for this acquisition is incomplete, pending identification and measurement of assets acquired and liabilities assumed.

In connection with our acquisition of Horizon, we entered into several debt and financing arrangements. See Note 10, Financing arrangements.

Acquisition of ChemoCentryx, Inc.

On October 20, 2022, we acquired all of the outstanding stock of ChemoCentryx, a publicly traded biotechnology company focused on orally administered therapeutics to treat autoimmune diseases, inflammatory disorders and cancer, for $52.00 per share in cash, representing a total consideration of $3.9 billion. The acquisition, which was accounted for as a business combination, includes TAVNEOS, an orally administered selective complement 5a receptor inhibitor that was approved by the FDA in October 2021 as an adjunctive therapy for adults with severe active antineutrophil cytoplasmic autoantibody-associated vasculitis (ANCA-associated vasculitis). TAVNEOS is commercialized by us in the United States; for markets outside the United States, TAVNEOS is commercialized by a collaboration partner, and Amgen is entitled to royalties and milestones based on future sales of the product. Upon its acquisition, ChemoCentryx became a wholly owned subsidiary of Amgen, and its operations became included in our consolidated financial statements commencing on the acquisition date.

Measurement period adjustments during the nine months ended September 30, 2023, included changes in the purchase price allocation and total consideration, resulting in a net decrease of approximately $18 million to goodwill. The measurement period adjustments resulted primarily from valuation inputs pertaining to the TAVNEOS intangible assets, adjustments to vendor payables and deferred tax attributes based on facts and circumstances that existed as of the acquisition date and did not result from events subsequent to the acquisition date. The adjustments did not have a significant impact on Amgen's results of operations during the nine months ended September 30, 2023, and would not have had a significant impact on prior-period results if the adjustments had been made as of the acquisition date.

The following table summarizes the final total consideration and allocated acquisition date fair values of assets acquired and liabilities assumed, inclusive of measurement period adjustments (in millions):

	Amounts
Cash and cash equivalents	$ 86
Marketable securities	235
Inventories	41
Finite-lived intangible assets—developed-product-technology rights	3,499
Goodwill	649
Other liabilities, net	(83)
Deferred tax liability, net	(502)
Total assets acquired, net	$ 3,925

The $3.9 billion total consideration consisted of (i) a $3.7 billion cash payment to outstanding common stockholders of ChemoCentryx and (ii) a $181 million cash payment to equity award holders of ChemoCentryx for services rendered prior to the acquisition date of October 20, 2022, under the ChemoCentryx equity award plans.

The developed-product-technology rights acquired relates to TAVNEOS, which is approved in the United States and the EU for ANCA-associated vasculitis. The estimated fair values of $3.5 billion were determined by using a multi-period excess earnings income approach that discounts expected future cash flows to present value by applying a discount rate that represents the estimated rate that market participants would use to value the intangible assets. The developed-product-technology rights are being amortized on a straight-line basis over a weighted-average period of approximately 11 years using the straight-line method.

The estimated fair value of the acquired inventory of $41 million was determined using the comparative sales method, which uses actual or expected selling prices of inventory as the base amount to which adjustments for selling effort and a profit on the buyer's effort are applied. The inventory fair value adjustment is being amortized as inventory turns over, which we estimate to be approximately 13 months.

A net deferred tax liability of $502 million was recognized on the temporary differences related to the book bases and tax bases of the acquired identifiable assets and assumed liabilities, primarily driven by the intangible assets acquired.

The excess of the acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $649 million was recorded as goodwill, which is not deductible for tax purposes. The goodwill value is primarily attributable to the expected synergies from the TAVNEOS asset.

Divestiture of Gensenta İlaç Sanayi ve Ticaret A.Ş.

On November 2, 2022, we sold our shares in Gensenta, a subsidiary in Turkey, to Eczacıbaşı for net cash proceeds of approximately $130 million. The transaction was accounted for as a sale of a business and did not meet the criteria to be classified as discontinued operations. Upon closing of this transaction, net assets related to Gensenta of $86 million were divested, and during the year ended December 31, 2022, we recognized a loss on divestiture of $567 million recorded in Other operating expenses in the Consolidated Statements of Income, primarily due to the reclassification of $615 million of cumulative foreign currency translation losses from AOCI into earnings.

4. 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 ROW revenues relates to products sold in Europe.

Revenues were as follows (in millions):

	Three months ended September 30,					
	2023			2022		
	U.S.	ROW	Total	U.S.	ROW	Total
Prolia	$ 673	$ 313	$ 986	$ 590	$ 272	$ 862
ENBREL	1,026	9	1,035	1,086	20	1,106
XGEVA	374	145	519	363	132	495
Otezla	462	105	567	529	98	627
Repatha	183	223	406	142	167	309
Nplate	322	97	419	162	126	288
KYPROLIS	231	118	349	217	101	318
Aranesp	107	216	323	128	230	358
EVENITY	214	93	307	136	65	201
Other products[1]	1,099	538	1,637	1,113	560	1,673
Total product sales[2]	$ 4,691	$ 1,857	6,548	$ 4,466	$ 1,771	6,237
Other revenues			355			415
Total revenues			$ 6,903			$ 6,652

	Nine months ended September 30,					
	2023			2022		
	U.S.	ROW	Total	U.S.	ROW	Total
Prolia	$ 1,987	$ 954	$ 2,941	$ 1,783	$ 853	$ 2,636
ENBREL	2,645	37	2,682	2,965	54	3,019
XGEVA	1,145	440	1,585	1,122	408	1,530
Otezla	1,251	308	1,559	1,366	306	1,672
Repatha	592	626	1,218	461	502	963
Nplate	744	347	1,091	474	364	838
KYPROLIS	699	354	1,053	626	296	922
Aranesp	345	698	1,043	397	676	1,073
EVENITY	570	272	842	376	186	562
Other products[1]	3,424	1,639	5,063	3,379	1,655	5,034
Total product sales[2]	$ 13,402	$ 5,675	19,077	$ 12,949	$ 5,300	18,249
Other revenues			917			1,235
Total revenues			$ 19,994			$ 19,484

[1] Consists of product sales of our non-principal products as well as sales in prior periods of our divested Bergamo and Gensenta subsidiaries.

[2] Hedging gains and losses, which are included in product sales, were not material for the three and nine months ended September 30, 2023 and 2022.

5. Income taxes

The effective tax rates for the three and nine months ended September 30, 2023, were 11.1% and 15.0%, respectively, compared with 10.4% and 11.8%, respectively, for the corresponding periods in the prior year.

The increase in our effective tax rate for the three months ended September 30, 2023, was primarily due to the 2022 Puerto Rico tax law change that replaced the excise tax with an income tax beginning in 2023, partially offset by a prior year nondeductible loss from the divestiture of Gensenta and net earnings mix including the tax benefit from a net impairment charge related to AMG 340. See Note 9, Goodwill and other intangible assets. The increase in our effective tax rate for the nine months ended September 30, 2023, was primarily due to the 2022 Puerto Rico tax law change that replaced the excise tax with an income tax beginning in 2023 and net change in earnings mix, partially offset by a prior year nondeductible loss from the divestiture of Gensenta. The effective tax rates differ from the federal statutory rate primarily as a result of foreign earnings from the Company's operations conducted in Puerto Rico, a territory of the United States treated as a foreign jurisdiction for U.S. tax purposes, that are currently subject to a tax incentive grant through 2050. In addition, the Company's operations conducted in Singapore are subject to a tax incentive grant through 2036. These foreign earnings are also subject to U.S. tax at a reduced rate of 10.5%.

We are no longer subject to a 4% excise tax in the U.S. territory of Puerto Rico on the gross intercompany purchase price of goods and services from our manufacturer in Puerto Rico. As of January 1, 2023, we qualify for and are subject to the alternative income tax rate on industrial development income of our Puerto Rico affiliate. In the United States, this income tax qualifies for foreign tax credits. Both this income tax and the associated foreign tax credits are generally recognized in our provision for income taxes. We accounted for the 2022 excise tax that was capitalized in Inventories as an expense in Cost of sales when the related products were sold in 2023, and a foreign tax credit was not recognized in 2023 with respect to the excise 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 and have arisen 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. Tax authorities, including the IRS, are becoming more aggressive and are particularly focused on such matters.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010–2012, proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS appeals office but were unable to reach resolution. In July 2021, we filed a petition in the U.S. Tax Court to contest two duplicate Statutory Notices of Deficiency (Notices) for the years 2010–2012 that we received in May and July 2021, which seek to increase our U.S. taxable income for the years 2010–2012 by an amount that would result in additional federal tax of approximately $3.6 billion plus interest. Any additional tax that could be imposed for the years 2010–2012 would be reduced by up to approximately $900 million of repatriation tax previously accrued on our foreign earnings.

In 2020, we received an RAR and a modified RAR from the IRS for the years 2013–2015, 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 2010–2012. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS appeals office but were unable to reach resolution. In July 2022, we filed a petition in the U.S. Tax Court to contest a Notice for the years 2013–2015 that we previously reported receiving in April 2022 that seeks to increase our U.S. taxable income for the years 2013–2015 by an amount that would result in additional federal tax of approximately $5.1 billion, plus interest. In addition, the Notice asserts penalties of approximately $2.0 billion. Any additional tax that could be imposed for the years 2013–2015 would be reduced by up to approximately $2.2 billion of repatriation tax previously accrued on our foreign earnings.

We firmly believe that the IRS positions set forth in the 2010–2012 and 2013–2015 Notices are without merit. We are contesting the 2010–2012 and 2013–2015 Notices through the judicial process. The two cases were consolidated in the U.S. Tax Court on December 19, 2022. On February 10, 2023, the U.S. Tax Court entered an order setting a trial date of November 4, 2024.

We are currently under examination by the IRS for the years 2016–2018 with respect to issues similar to those for the 2010 through 2015 period. In addition, we are under examination by a number of 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 impact on our condensed consolidated financial statements.

We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009.

See our Annual Report on Form 10-K for the year ended December 31, 2022, Part I, Item 1A, Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability,* for further discussion.

During the three and nine months ended September 30, 2023, the gross amounts of our UTBs increased by $50 million and $160 million, respectively, as a result of tax positions taken during the current year. Substantially all of the UTBs as of September 30, 2023, if recognized, would affect our effective tax rate.

6. Earnings per share

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Income (Numerator):				
Net income for basic and diluted EPS	$ 1,730	$ 2,143	$ 5,950	$ 4,936
Shares (Denominator):				
Weighted-average shares for basic EPS	535	535	535	539
Effect of dilutive securities	3	3	3	3
Weighted-average shares for diluted EPS	538	538	538	542
Basic EPS	$ 3.23	$ 4.01	$ 11.12	$ 9.16
Diluted EPS	$ 3.22	$ 3.98	$ 11.06	$ 9.11

For the three and nine months ended September 30, 2023 and 2022, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

7. Investments

Available-for-sale investments

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

Types of securities as of September 30, 2023	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury bills	$ —	$ —	$ —	$ —
Money market mutual funds	34,208	—	—	34,208
Total interest-bearing securities	$ 34,208	$ —	$ —	$ 34,208

Types of securities as of December 31, 2022	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury bills	$ 1,676	$ —	$ —	$ 1,676
Money market mutual funds	2,659	—	—	2,659
Total interest-bearing securities	$ 4,335	$ —	$ —	$ 4,335

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

Condensed Consolidated Balance Sheets locations	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 34,208	$ 2,659
Marketable securities	—	1,676
Total interest-bearing securities	$ 34,208	$ 4,335

Cash and cash equivalents in the above table excludes bank account cash of $533 million and $4,970 million as of September 30, 2023 and December 31, 2022, respectively.

Cash and cash equivalents as of September 30, 2023, was $34.7 billion, a majority of which was used to acquire Horizon in October 2023. See Note 3, Acquisitions and divestitures.

All interest-bearing securities as of September 30, 2023 and December 31, 2022, mature in one year or less.

For the three and nine months ended September 30, 2023 and 2022, realized gains and losses on interest-bearing securities were not material. Realized gains and losses on interest-bearing securities are recorded in Other income (expense), net, in the Condensed Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

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

Equity securities

BeiGene, Ltd.

Effective January 30, 2023, we relinquished our right to appoint a director to BeiGene's Board of Directors. We no longer have the ability to exert significant influence over BeiGene. As a result, in the first quarter of 2023, we began to account for our ownership interest as an equity security with a readily determinable fair value, with changes in fair value recorded in Other income (expense), net. See Note 12, Fair value measurement. During the three and nine months ended September 30, 2023, we recognized unrealized gains of $30 million and $1.2 billion, respectively, recorded in Other income (expense), net, in our Condensed Consolidated Statements of Income. As of September 30, 2023, the carrying and fair value of our investment in BeiGene was $3.4 billion and was included in Other noncurrent assets in the Condensed Consolidated Balance Sheets.

As of December 31, 2022, under the equity method of accounting, the carrying value of our investment in BeiGene was $2.2 billion and was included in Other noncurrent assets in the Condensed Consolidated Balance Sheets, and our ownership percentage was 18.2%. During the three and nine months ended September 30, 2022, under the equity method of accounting, our carrying value in BeiGene was adjusted by our share of BeiGene's net losses of $104 million and $292 million, respectively, and amortization of the basis difference of $48 million and $143 million, respectively, recorded in Other income (expense), net, in our Condensed Consolidated Statements of Income.

Other equity securities

Excluding our equity investments in BeiGene and Neumora (discussed below), we held investments in other equity securities with readily determinable fair values (publicly traded securities) of $344 million and $480 million as of September 30, 2023 and December 31, 2022, respectively, which are included in Other noncurrent assets in the Condensed Consolidated Balance Sheets. During the three months ended September 30, 2023 and 2022, net unrealized losses and gains on these publicly traded securities were a net loss of $49 million and a net gain of $17 million, respectively. During the nine months ended September 30, 2023 and 2022, net unrealized losses on these publicly traded securities were $41 million and $259 million, respectively. Realized gains and losses on sales of publicly traded securities for the three and nine months ended September 30, 2023 and 2022, were not material.

We held investments of $293 million and $233 million in equity securities without readily determinable fair values as of September 30, 2023 and December 31, 2022, respectively, which are included in Other noncurrent assets in the Condensed Consolidated Balance Sheets. During the three and nine months ended September 30, 2023, upward and downward adjustments on these securities were not material. During the three and nine months ended September 30, 2022, downward adjustments on these securities were $55 million and $64 million, respectively, and upward adjustments for these periods were not material. Adjustments were based on observable price transactions.

Equity method investments

Neumora Therapeutics, Inc.

On September 30, 2021, we acquired an approximately 25.9% ownership interest in Neumora, a then privately held company, for $257 million, which is included in Other noncurrent assets in the Condensed Consolidated Balance Sheets, in exchange for a $100 million cash payment and $157 million in noncash consideration primarily related to future services. During the three months ended September 30, 2023, we made an additional $30 million equity investment in Neumora in connection with their initial public stock offering, and consequently, our investment now has a readily determinable fair value. Although our equity investment provides us with the ability to exercise significant influence over Neumora and therefore qualifies us for the equity method of accounting, we have elected the fair value option to account for our investment. Under the fair value option, changes in the fair value of the investment are recognized through earnings in Other income (expense), net, in our Condensed Consolidated Statements of Income each reporting period. We believe the fair value option best reflects the economics of the underlying transaction. As of September 30, 2023 and December 31, 2022, our ownership interests in Neumora were approximately 23.2% and 24.9%, respectively, and the fair values of our investment were $499 million and $335 million, respectively. During the three months ended September 30, 2023 and 2022, we recognized gains of $153 million and $240 million, respectively, and during the nine months ended September 30, 2023 and 2022, we recognized gains of $134 million and $152 million, respectively.

For information on determination of fair values, see Note 12, Fair value measurement.

Limited partnerships

We held limited partnership investments of $238 million and $249 million as of September 30, 2023 and December 31, 2022, respectively, which are included in Other noncurrent assets in the Condensed Consolidated Balance Sheets. These investments, primarily investment funds of early-stage biotechnology companies, are accounted for by using the equity method of accounting and are measured by using our proportionate share of the net asset values of the underlying investments held by the limited partnerships as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of September 30, 2023, unfunded additional commitments to be made for these investments during the next several years amounted to $138 million. For the three months ended September 30, 2023 and 2022, net unrealized gains and losses from our limited partnership investments were an unrealized gain of $14 million and an unrealized loss of $62 million, respectively. For the nine months ended September 30, 2023 and 2022, net unrealized gains and losses from our limited partnership investments were an unrealized gain of $5 million and an unrealized loss of $282 million, respectively.

8. Inventories

Inventories consisted of the following (in millions):

	September 30, 2023	December 31, 2022
Raw materials	$ 849	$ 828
Work in process	2,992	3,098
Finished goods	1,185	1,004
Total inventories	$ 5,026	$ 4,930

9. Goodwill and other intangible assets

Goodwill

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

	Nine months ended September 30, 2023
Beginning balance	$ 15,529
Adjustments to goodwill resulting from acquisitions and divestitures, net	(22)
Currency translation adjustment	2
Ending balance	$ 15,509

Other intangible assets

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

	September 30, 2023			December 31, 2022		
	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	$ 29,028	$ (16,931)	$ 12,097	$ 29,028	$ (15,045)	$ 13,983
Licensing rights	3,864	(3,233)	631	3,864	(3,123)	741
Marketing-related rights	1,339	(1,243)	96	1,326	(1,167)	159
Research and development technology rights	1,377	(1,209)	168	1,378	(1,190)	188
Total finite-lived intangible assets	35,608	(22,616)	12,992	35,596	(20,525)	15,071
Indefinite-lived intangible assets:						
In-process research and development	158	—	158	1,009	—	1,009
Total other intangible assets	$ 35,766	$ (22,616)	$ 13,150	$ 36,605	$ (20,525)	$ 16,080

Developed-product-technology rights consists of rights related to marketed products. Licensing rights primarily consists of contractual rights to receive future milestone, royalty and profit-sharing payments; capitalized payments to third parties for milestones related to regulatory approvals to commercialize products; and upfront payments associated with royalty obligations for marketed products. Marketing-related rights primarily consists of rights related to the sale and distribution of marketed products. R&D technology rights pertains to technologies used in R&D that have alternative future uses.

IPR&D consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. We review IPR&D projects for impairment annually, whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable and upon the establishment of technological feasibility or regulatory approval. During the three months ended September 30, 2023, the development of AMG 340 acquired in connection with our Teneobio acquisition was terminated, resulting in an impairment charge of $783 million, which was recognized in Other operating expenses in the Condensed Consolidated Statements of Income and included in Other items, net, in the Condensed Consolidated Statements of Cash Flows. See Note 12, Fair value measurement, for the impact on the related contingent consideration liability.

During the three months ended September 30, 2023 and 2022, we recognized amortization associated with our finite-lived intangible assets of $693 million and $628 million, respectively. During the nine months ended September 30, 2023 and 2022, we recognized amortization associated with our finite-lived intangible assets of $2.1 billion and $1.9 billion, respectively. Amortization of intangible assets is primarily included in Cost of sales in the Condensed Consolidated Statements of Income. As of September 30, 2023, the total estimated amortization of our finite-lived intangible assets for the remaining three months ending December 31, 2023, and the years ending December 31, 2024, 2025, 2026, 2027 and 2028, are $0.7 billion, $2.7 billion, $2.5 billion, $2.1 billion, $2.1 billion and $1.1 billion, respectively.

10. Financing arrangements

Our borrowings consisted of the following (in millions):

	September 30, 2023	December 31, 2022
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	$ —	$ 757
2.25% notes due 2023 (2.25% 2023 Notes)	—	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
5.25% notes due 2025 (5.25% 2025 Notes)	2,000	—
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)	793	803
5.507% notes due 2026 (5.507% 2026 Notes)	1,500	—
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)	579	574
2.20% notes due 2027 (2.20% 2027 Notes)	1,724	1,724
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
5.15% notes due 2028 (5.15% 2028 Notes)	3,750	—
1.65% notes due 2028 (1.65% 2028 Notes)	1,234	1,234
3.00% notes due 2029 (3.00% 2029 Notes)	750	750
4.05% notes due 2029 (4.05% 2029 Notes)	1,250	1,250
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	855	846
2.45% notes due 2030 (2.45% 2030 Notes)	1,250	1,250
5.25% notes due 2030 (5.25% 2030 Notes)	2,750	—
2.30% notes due 2031 (2.30% 2031 Notes)	1,250	1,250
2.00% notes due 2032 (2.00% 2032 Notes)	1,001	1,051
3.35% notes due 2032 (3.35% 2032 Notes)	1,000	1,000
4.20% notes due 2033 (4.20% 2033 Notes)	750	750
5.25% notes due 2033 (5.25% 2033 Notes)	4,250	—
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)	1,803	2,000
5.75% notes due 2040 (5.75% 2040 Notes)	373	373
2.80% notes due 2041 (2.80% 2041 Notes)	1,091	1,110
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
5.60% notes due 2043 (5.60% 2043 Notes)	2,750	—
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)	2,132	2,250
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
3.00% notes due 2052 (3.00% 2052 Notes)	999	1,254
4.20% notes due 2052 (4.20% 2052 Notes)	950	1,000
4.875% notes due 2053 (4.875% 2053 Notes)	1,000	1,000
5.65% notes due 2053 (5.65% 2053 Notes)	4,250	—
2.77% notes due 2053 (2.77% 2053 Notes)	940	940
4.40% notes due 2062 (4.40% 2062 Notes)	1,200	1,250

	September 30, 2023	December 31, 2022
5.75% notes due 2063 (5.75% 2063 Notes)	2,750	—
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(1,423)	(1,246)
Fair value adjustments	(494)	(437)
Other	11	12
Total carrying value of debt	60,468	38,945
Less current portion	(1,428)	(1,591)
Total long-term debt	$ 59,040	$ 37,354

There are no material differences between the effective interest rates and coupon rates of any of our borrowings, except for the 4.563% 2048 Notes, the 4.663% 2051 Notes and the 2.77% 2053 Notes, which have effective interest rates of 6.3%, 5.6% and 5.2%, respectively.

Debt issuances and acquisition-related financing

During the three months ended March 31, 2023, in connection with the acquisition of Horizon (see Note 3, Acquisitions and divestitures—*Acquisition of Horizon Therapeutics plc*), we issued the following series of notes (in millions):

	Principal Amount
5.25% 2025 Notes	$ 2,000
5.507% 2026 Notes	1,500
5.15% 2028 Notes	3,750
5.25% 2030 Notes	2,750
5.25% 2033 Notes	4,250
5.60% 2043 Notes	2,750
5.65% 2053 Notes	4,250
5.75% 2063 Notes	2,750
Total	$ 24,000

In the event of a change-in-control triggering event, as defined by the terms of the notes, we may be required to purchase all or a portion of these notes at a price equal to 101% of the principal amount of the notes plus accrued and unpaid interest. In addition, these notes may be redeemed at any time at our option, in whole or in part, at the principal amount of the notes being redeemed plus accrued and unpaid interest and a make-whole amount, which are defined by the terms of the notes. Except with respect to the 5.25% 2025 Notes, the notes may be redeemed without payment of make-whole amounts if redemption occurs during a specified period of time immediately prior to the maturing of the notes. Such time periods range from two months to six months prior to maturity, except for the 5.507% 2026 Notes, which may be redeemed without payment of the make-whole amount if redemption occurs after two years prior to maturity.

In December 2022, in connection with the acquisition of Horizon, we entered into a bridge credit agreement, which provided for borrowings with an aggregate principal amount of $24.5 billion as of December 31, 2022. Subsequent to our March 2023 debt issuance described above, we terminated the bridge credit agreement. Accordingly, during the three months ended March 31, 2023, we recognized $98 million of financing cost associated with the bridge credit agreement, primarily in Other income (expense), net, in the Condensed Consolidated Statements of Income.

Also in connection with the acquisition of Horizon, we entered into a $4.0 billion term loan credit agreement in December 2022. No amounts under this agreement were outstanding as of September 30, 2023 and December 31, 2022. In October 2023, in connection with the completion of the acquisition of Horizon, we borrowed $4.0 billion under the term loan credit agreement with an interest rate of three-month SOFR plus 1.225%, of which $2.0 billion is due in April 2025 and $2.0 billion is due in October 2026.

Debt extinguishment

During the nine months ended September 30, 2023, we repurchased portions of the 2.00% 2032 Notes, 3.15% 2040 Notes, 2.80% 2041 Notes, 3.375% 2050 Notes, 3.00% 2052 Notes, 4.20% 2052 Notes and 4.40% 2062 Notes for an aggregate cost of $550 million, which resulted in the recognition of a $182 million gain on extinguishment of debt recorded in Other income (expense), net, in the Condensed Consolidated Statements of Income.

Debt repayments

During the nine months ended September 30, 2023, we repaid $750 million aggregate principal amount of the 2.25% 2023 Notes as well as the CHF700 million aggregate principal amount ($704 million upon settlement of the related cross-currency swap) of the 0.41% 2023 Swiss franc Bonds.

Shelf registration statement and other facilities

In February 2023, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time, with terms to be determined at the time of issuance. This shelf registration statement expires in February 2026.

During the three months ended March 31, 2023, we amended and restated our syndicated, unsecured, revolving credit agreement, under which we may borrow up to $4.0 billion (increased from $2.5 billion prior to the amendment) for general corporate purposes, including as a liquidity backstop for our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $1.25 billion with the agreement of the banks (increased from $750 million prior to the amendment). Each bank that is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest for any amounts borrowed under this facility, based on our current credit rating, at (i) SOFR plus 1.01% or (ii) the highest of (A) the administrative agent bank base commercial lending rate, (B) the overnight federal funds rate plus 0.50% or (C) one-month SOFR plus 1.1%. As of September 30, 2023 and December 31, 2022, no amounts were outstanding under this facility.

11. Stockholders' equity

Stock repurchase program

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

	2023		2022	
	Shares	Dollars	Shares	Dollars
First quarter	—	$ —	24.6	$ 5,410
Second quarter	—	—	—	—
Third quarter	—	—	1.5	900
Total stock repurchases	—	$ —	26.1	$ 6,310

As of September 30, 2023, $7.0 billion of authorization remained available under our stock repurchase program.

Dividends

In August 2023, March 2023 and December 2022, our Board of Directors declared quarterly cash dividends of $2.13 per share, which were paid in September 2023, June 2023 and March 2023, respectively. In October 2023, our Board of Directors declared a quarterly cash dividend of $2.13 per share that will be paid in December 2023.

Accumulated other comprehensive income (loss)

The components of AOCI were as follows (in millions):

	Foreign currency translation	Cash flow hedges	Other	AOCI
Balance as of December 31, 2022	$ (348)	$ 128	$ (11)	$ (231)
Foreign currency translation adjustments	28	—	—	28
Unrealized losses	—	(71)	—	(71)
Reclassification adjustments to income	—	(30)	—	(30)
Other	—	—	21	21
Income taxes	—	15	—	15
Balance as of March 31, 2023	(320)	42	10	(268)
Foreign currency translation adjustments	11	—	—	11
Unrealized gains	—	50	—	50
Reclassification adjustments to income	—	(87)	—	(87)
Other	—	—	(1)	(1)
Income taxes	—	15	—	15
Balance as of June 30, 2023	(309)	20	9	(280)
Foreign currency translation adjustments	(44)	—	—	(44)
Unrealized gains	—	177	—	177
Reclassification adjustments to income	—	53	—	53
Other	—	—	17	17
Income taxes	—	(49)	—	(49)
Balance as of September 30, 2023	$ (353)	$ 201	$ 26	$ (126)

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

	Three months ended September 30,		
Components of AOCI	**2023**	**2022**	**Condensed Consolidated Statements of Income locations**
Cash flow hedges:			
Foreign currency contract gains	$ 33	$ 69	Product sales
Cross-currency swap contract losses	(86)	(198)	Other income (expense), net
	(53)	(129)	Income before income taxes
	11	28	Provision for income taxes
	$ (42)	$ (101)	Net income

	Nine months ended September 30,		
Components of AOCI	**2023**	**2022**	**Condensed Consolidated Statements of Income locations**
Cash flow hedges:			
Foreign currency contract gains	$ 121	$ 149	Product sales
Cross-currency swap contract losses	(57)	(461)	Other income (expense), net
	64	(312)	Income before income taxes
	(14)	67	Provision for income taxes
	$ 50	$ (245)	Net income

12. Fair value measurement

To estimate the fair value of our financial assets and liabilities, we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing an asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing an asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the sources 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 different types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

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

Fair value measurement as of September 30, 2023, 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 bills	$ —	$ —	$ —	$ —
Money market mutual funds	34,208	—	—	34,208
Other investments	—	136	—	136
Equity securities	4,250	—	—	4,250
Derivatives:				
Foreign currency forward contracts	—	347	—	347
Cross-currency swap contracts	—	—	—	—
Total assets	$ 38,458	$ 483	$ —	$ 38,941
Liabilities:				
Derivatives:				
Foreign currency forward contracts	$ —	$ 29	$ —	$ 29
Cross-currency swap contracts	—	513	—	513
Interest rate swap contracts	—	772	—	772
Forward interest rate contracts	—	—	—	—
Contingent consideration obligations	—	—	98	98
Total liabilities	$ —	$ 1,314	$ 98	$ 1,412

Fair value measurement as of December 31, 2022, 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 bills	$ 1,676	$ —	$ —	$ 1,676
Money market mutual funds	2,659	—	—	2,659
Other investments	—	130	—	130
Equity securities	480	—	335	815
Derivatives:				
Foreign currency forward contracts	—	287	—	287
Cross-currency swap contracts	—	54	—	54
Total assets	$ 4,815	$ 471	$ 335	$ 5,621
Liabilities:				
Derivatives:				
Foreign currency forward contracts	$ —	$ 76	$ —	$ 76
Cross-currency swap contracts	—	541	—	541
Interest rate swap contracts	—	776	—	776
Forward interest rate contracts	—	5	—	5
Contingent consideration obligations	—	—	270	270
Total liabilities	$ —	$ 1,398	$ 270	$ 1,668

Interest-bearing and equity securities

The fair values of our U.S. Treasury securities, money market mutual funds and equity investments in publicly traded securities, including our equity investments in BeiGene and Neumora, as of September 30, 2023, are based on quoted market prices in active markets, with no valuation adjustment. Other investments consist of interest-bearing deposits that are valued at amortized cost, which approximates fair value given their near-term maturity. Previously, the fair value of our equity investment in Neumora did not have a readily determinable fair value and was initially valued at the acquisition price and subsequently valued based on a combination of observable price transactions when available, market performance and publicly available market information for similar companies that have actively traded equity securities. During the three months ended September 30, 2023, Neumora became a publicly traded company, and its equity securities now have a readily determinable fair value. Accordingly, the fair value inputs of our equity investment in Neumora changed from using Level 3 inputs as of December 31, 2022, to using a Level 1 input as of September 30, 2023. See Note 7, Investments—*Neumora Therapeutics, Inc.*

As of the first quarter of 2023, we no longer account for our equity investment in BeiGene under the equity method of accounting. As of December 31, 2022, the fair value and carrying value were $4.2 billion and $2.2 billion, respectively, with the fair value estimated by using a Level 1 input. See Note 7, Investments—*BeiGene, Ltd.*

Derivatives

All of our foreign currency forward contracts, cross-currency swap contracts and 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 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, as applicable, include foreign currency exchange rates, LIBOR, SOFR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. Certain inputs, when applicable, are at commonly quoted intervals. Starting in the third quarter of 2023, terms under our existing derivative contracts reference the SOFR benchmark consistent with the ISDA protocol. See Note 13, Derivative instruments.

Contingent consideration obligations

As a result of our business acquisitions, we have incurred contingent consideration obligations as discussed below. The contingent consideration obligations are recorded at their fair values by using probability-adjusted discounted cash flows, and we revalue these obligations each reporting period until the related contingencies have been resolved. The fair value measurements of these obligations are based on significant unobservable inputs related to licensing rights and product candidates acquired in business combinations, and they are reviewed quarterly by management in our R&D and commercial sales organizations. The inputs include, as applicable, estimated probabilities and the timing of achieving specified development, regulatory and commercial milestones as well as estimated annual sales. Significant changes that increase or decrease the probabilities of achieving the related development, regulatory and commercial events or that shorten or lengthen the time required to achieve such events or that increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of the obligations, as applicable. Changes in the fair values of contingent consideration obligations are recognized in Other operating expenses in the Condensed Consolidated Statements of Income.

Changes in the carrying amounts of contingent consideration obligations were as follows (in millions):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Beginning balance	$ 248	$ 310	$ 270	$ 342
Payments	(3)	(2)	(7)	(5)
Net changes in valuations	(147)	(6)	(165)	(35)
Ending balance	$ 98	$ 302	$ 98	$ 302

As of September 30, 2023 and December 31, 2022, our contingent consideration obligations are primarily the result of our acquisition of Teneobio in October 2021, which obligated us to pay the former shareholders up to $1.6 billion upon achieving separate development and regulatory milestones with regard to various R&D programs. During the three months ended September 30, 2023, the development of AMG 340 was terminated, resulting in a decrease of the related contingent consideration liability. The remeasurement of this liability of $147 million was recognized in Other operating expenses in the Condensed Consolidated Statements of Income and included in Other items, net, in the Condensed Consolidated Statements of Cash Flows. See Note 9, Goodwill and other intangible assets, for the impact on the related IPR&D asset. The remaining contingent consideration liability as of September 30, 2023, primarily relates to potential development and regulatory milestones for R&D programs acquired via the Teneobio acquisition that we continue to pursue.

Summary of the fair values of other financial instruments

Cash equivalents

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

Borrowings

We estimated the fair values of our borrowings by using Level 2 inputs. As of September 30, 2023 and December 31, 2022, the aggregate fair values of our borrowings were $56.4 billion and $35.0 billion, respectively, and the carrying values were $60.5 billion and $38.9 billion, respectively.

During the nine months ended September 30, 2023 and 2022, there were no transfers of assets or liabilities between fair value measurement levels, and except with respect to the impairment of AMG 340 discussed in Note 9, Goodwill and other intangible assets, there were no material remeasurements to the fair values of assets and liabilities that are not measured at fair value on a recurring basis.

13. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we use or have used certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We have designated certain of our derivatives as cash flow and fair value hedges; we also have derivatives not designated as hedges. 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. The foreign currency exchange rate fluctuation exposure associated with cash inflows from our international product sales is partially offset by corresponding cash outflows from our international operating expenses. To further reduce our exposure, we enter into foreign currency forward contracts to hedge a portion of our projected international product sales up to a maximum of three years into the future; and at any given point in time, a higher percentage of nearer-term projected product sales is being hedged than in successive periods.

As of September 30, 2023 and December 31, 2022, we had outstanding foreign currency forward contracts with aggregate notional amounts of $6.3 billion and $6.0 billion, respectively. We have designated these foreign currency forward contracts, which are primarily euro based, as cash flow hedges. Accordingly, we report the unrealized gains and losses on these contracts in AOCI in the Condensed Consolidated Balance Sheets, and we reclassify them to Product sales in the Condensed Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

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

The notional amounts and interest rates of our cross-currency swaps as of September 30, 2023, were as follows (notional amounts in millions):

	Foreign currency			U.S. dollars	
Hedged notes	**Notional amounts**		**Interest rates**	**Notional amounts**	**Interest rates**
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	4.6 %

During the three months ended March 31, 2023, our 0.41% 2023 Swiss franc Bonds matured, and the related cross-currency swaps were settled.

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Condensed Consolidated Balance Sheets and are amortized into Interest expense, net, in the Condensed Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate contracts during the nine months ended September 30, 2023, and amounts expected to be recognized during the subsequent 12 months are not material.

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

Derivatives in cash flow hedging relationships	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Foreign currency forward contracts	$ 198	$ 324	$ 222	$ 654
Cross-currency swap contracts	(22)	(279)	(36)	(486)
Forward interest rate contracts	—	—	(31)	—
Total unrealized gains	$ 176	$ 45	$ 155	$ 168

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 coupons over the terms of the related hedge contracts. As of both September 30, 2023 and December 31, 2022, we had interest rate swap contracts with aggregate notional amounts of $6.7 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):

Condensed Consolidated Balance Sheets locations	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
	September 30, 2023	December 31, 2022	September 30, 2023	December 31, 2022
Current portion of long-term debt	$ 1,426	$ 82	$ 27	$ 82
Long-term debt	$ 4,621	$ 6,017	$ (521)	$ (519)

[1] Current portion of long-term debt includes $75 million and $82 million of carrying value with discontinued hedging relationships as of September 30, 2023 and December 31, 2022, respectively. Long-term debt includes $303 million and $357 million of carrying value with discontinued hedging relationships as of September 30, 2023 and December 31, 2022, respectively.

[2] Current portion of long-term debt includes $75 million and $82 million of hedging adjustments on discontinued hedging relationships as of September 30, 2023 and December 31, 2022, respectively. Long-term debt includes $203 million and $257 million of hedging adjustments on discontinued hedging relationships as of September 30, 2023 and December 31, 2022, respectively.

Impact of hedging transactions

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

	Three months ended September 30, 2023			Nine months ended September 30, 2023		
	Product sales	Other income (expense), net	Interest expense, net	Product sales	Other income (expense), net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Condensed Consolidated Statements of Income	$ 6,548	$ 685	$ (759)	$ 19,077	$ 2,431	$ (2,054)
The effects of cash flow and fair value hedging:						
Gains (losses) on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency forward contracts	$ 33	$ —	$ —	$ 121	$ —	$ —
Cross-currency swap contracts	$ —	$ (86)	$ —	$ —	$ (57)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:						
Hedged items[1]	$ —	$ —	$ 58	$ —	$ —	$ 63
Derivatives designated as hedging instruments	$ —	$ —	$ (37)	$ —	$ —	$ 5

	Three months ended September 30, 2022			Nine months ended September 30, 2022		
	Product sales	Other income (expense), net	Interest expense, net	Product sales	Other income (expense), net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Condensed Consolidated Statements of Income	$ 6,237	$ 100	$ (368)	$ 18,249	$ (747)	$ (991)
The effects of cash flow and fair value hedging:						
Gains (losses) on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency forward contracts	$ 69	$ —	$ —	$ 149	$ —	$ —
Cross-currency swap contracts	$ —	$ (198)	$ —	$ —	$ (461)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:						
Hedged items[1]	$ —	$ —	$ 240	$ —	$ —	$ 734
Derivatives designated as hedging instruments	$ —	$ —	$ (220)	$ —	$ —	$ (670)

[1] Gains on hedged items do not exactly offset losses on the related designated hedging instruments due to amortization of the cumulative amounts of fair value hedging adjustments included in the carrying amount of the hedged debt for discontinued hedging relationships and the recognition of gains on terminated hedges when the corresponding hedged item was paid down in the period.

No portions of our cash flow hedge contracts were excluded from the assessment of hedge effectiveness. As of September 30, 2023, we expected to reclassify $200 million of net gains on our foreign currency and cross-currency swap contracts out of AOCI and into earnings during the next 12 months.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations in certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. Most of these exposures are hedged on a month-to-month basis. As of September 30, 2023 and December 31, 2022, the total notional amounts of these foreign currency forward contracts were $521 million and $517 million, respectively. Gains and losses recognized in earnings for our derivative instruments not designated as hedging instruments were not material for the three and nine months ended September 30, 2023 and 2022.

Fair values of derivatives

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

	Derivative assets		Derivative liabilities	
September 30, 2023	**Condensed Consolidated Balance Sheets locations**	**Fair values**	**Condensed Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency forward contracts	Other current assets/ Other noncurrent assets	$ 347	Accrued liabilities/ Other noncurrent liabilities	$ 29
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	513
Interest rate swap contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	772
Forward interest rate contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	—
Total derivatives designated as hedging instruments		347		1,314
Total derivatives		$ 347		$ 1,314

	Derivative assets		Derivative liabilities	
December 31, 2022	**Condensed Consolidated Balance Sheets locations**	**Fair values**	**Condensed Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency forward contracts	Other current assets/ Other noncurrent assets	$ 287	Accrued liabilities/ Other noncurrent liabilities	$ 76
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	54	Accrued liabilities/ Other noncurrent liabilities	541
Interest rate swap contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	776
Forward interest rate contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	5
Total derivatives designated as hedging instruments		341		1,398
Total derivatives		$ 341		$ 1,398

For additional information, see Note 12, Fair value measurement.

Our derivative contracts that were in liability positions as of September 30, 2023, 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 provided by (used in) financing activities.

14. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See our Annual Report on Form 10-K for the year ended December 31, 2022, Part I, Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations.* We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote; and 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, 2022; and in Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2023 and June 30, 2023.

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; and 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, 2022; and in Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2023 and June 30, 2023, 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; and 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, 2022; and in Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2023 and June 30, 2023, 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.

Repatha Patent Litigation

Patent Disputes in the International Region

On December 6, 2023, oral proceedings will commence before the Technical Board of Appeal of the European Patent Office in the appeal from Amgen's opposition to European Patent No. 2,756,004.

In Amgen's lawsuit before the Unitary Patent Court against Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie S.A. (collectively, Sanofi) and Regeneron Pharmaceuticals, Inc. (Regeneron), on August 25, 2023, the Central Division of the Unitary Patent Court in Germany rejected Amgen's objections to the admissibility of Sanofi's revocation action against Amgen's European Patent No. 3,666,797. Accordingly, Amgen filed its Statement of Defense on September 12, 2023.

On September 15, 2023, the Japanese Supreme Court declined to hear Amgen's appeal from the decision of the Japanese High Court finding Amgen's patent claims invalid for lacking adequate support. The case will be remanded to the Japan Patent Office for further proceedings.

In Amgen's lawsuit for patent infringement damages against Sanofi K.K., on September 27, 2023, the Tokyo District Court found Amgen's patent claims invalid and dismissed Amgen's lawsuit for damages.

Prolia/XGEVA Biologics Price Competition and Innovation Act (BPCIA) Litigation

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

On August 23, 2023, the U.S. District Court for the District of New Jersey (New Jersey District Court) entered a stipulation and order dismissing without prejudice Sandoz GmbH, Lek Pharmaceuticals d.d., Novartis Pharmaceutical Productions d.o.o. and Novartis AG (collectively "Foreign Defendants") from the action. Pursuant to the stipulation entered by the New Jersey District Court, the Foreign Defendants agreed to be bound by any judgment order or decision in the matter (including appeals) as if the Foreign Defendants were named as defendants and parties to the judgment order or decision. Sandoz Inc. (Sandoz) is now the sole named defendant in the action.

On October 30, 2023, the New Jersey District Court commenced a hearing on Amgen's motion for a preliminary injunction to prohibit Sandoz from engaging in the commercial manufacture, use, offer for sell or sale within the United States, or importation into the United States of its proposed denosumab biosimilar until judgment is entered after trial on the merits.

Antitrust Actions

Sensipar Antitrust Class Actions

On October 17, 2023, Amgen submitted its initial brief in its appeal before the U.S. Court of Appeals for the Third Circuit.

Regeneron Pharmaceuticals, Inc. Antitrust Action

On August 28, 2023, Regeneron filed its amended complaint, and on September 20, 2023, Amgen filed a counterclaim, alleging Regeneron's own anticompetitive conduct with respect to formulary position for Regeneron's drug, PRALUENT®, at CVS.

U.S. Tax Litigation and Related Matters

Amgen Inc. & Subsidiaries v. Commissioner of Internal Revenue

See Note 5, Income taxes, for discussion of the IRS tax dispute and the Company's petitions in the U.S. Tax Court.

Securities Class Action Litigation

On August 31, 2023, plaintiff filed an amended complaint. Amgen's motion to dismiss is due November 6, 2023.

Shareholder Derivative Litigation

On October 2, 2023, the U.S. District Court for the Southern District of New York granted a stay of the matter pending an outcome on the motion to dismiss in the federal securities class action filed by plaintiff.

ChemoCentryx, Inc. Securities Class Action Litigation

The due date for our subsidiary ChemoCentryx to file its opposition to class certification is November 22, 2023.

FTC Litigation re the Horizon Therapeutics plc Acquisition

On September 1, 2023, the FTC, the six state plaintiffs and Amgen announced that they entered into a consent agreement that resolved the matter, and both the federal litigation and the FTC administrative case were dismissed.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following 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, 2022, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2023 and June 30, 2023. 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 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, 2022, and in Part II, Item 1A. Risk Factors of our Quarterly Reports on Form 10-Q for the periods ended March 31, 2023 and June 30, 2023. 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 by discovering, developing, manufacturing and delivering innovative human therapeutics. 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 are Prolia, ENBREL, XGEVA, Otezla, Repatha, Nplate, KYPROLIS, Aranesp and EVENITY. We also market a number of other products, including Vectibix, BLINCYTO, MVASI, Neulasta, AMJEVITA/AMGEVITA, TEZSPIRE, Parsabiv, Aimovig, LUMAKRAS/LUMYKRAS, EPOGEN, KANJINTI and TAVNEOS.

Macroeconomic challenges

Uncertain macroeconomic conditions, including higher inflation, rising interest rates and instability in the financial system, as well as rising healthcare costs continue to pose challenges to our business. Further, ongoing geopolitical conflicts continue to create additional uncertainty in global macroeconomic conditions. As a result of public and private healthcare-provider focus, the industry continues to be subject to cost containment measures and significant pricing pressures, including net price declines. Moreover, legislation enacted to reduce healthcare expenditures, including provisions of the IRA, have affected, and are likely to continue to affect, our business. See our Quarterly Report on Form 10-Q for the period ended March 31, 2023, Part II, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business.*

Significant developments

Following is a summary of selected significant developments affecting our business that occurred since the filing of our Quarterly Report on Form 10-Q for the period ended June 30, 2023. 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, 2022, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2023 and June 30, 2023.

Acquisition of Horizon Therapeutics plc

On October 6, 2023, Amgen completed its acquisition of Horizon for $116.50 per share in cash, representing a transaction equity value of approximately $27.8 billion. Horizon is a global biotechnology company focused on the discovery, development and commercialization of medicines that address critical needs of patients impacted by rare, autoimmune and severe inflammatory diseases. The acquisition aligns with Amgen's core strategy of delivering innovative medicines that make a significant difference for patients suffering from serious diseases and strengthens Amgen's leading inflammation portfolio by adding first-in-class, early-in-lifecycle medicines such as TEPEZZA® (teprotumumab-trbw), KRYSTEXXA® (pegloticase) and UPLIZNA® (inebilizumab-cdon), which treat rare inflammatory diseases. See Part II, Item 1A. Risk Factors—*Our efforts to collaborate with or acquire other companies, products, or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions*, of this Quarterly Report.

Products/Pipeline

Tarlatamab

On October 20, 2023, we announced results from the global Phase 2 DeLLphi-301 study, evaluating tarlatamab, an investigational delta-like ligand 3 (DLL3) targeting BiTE® (bispecific T-cell engager) molecule, in patients with advanced stage small cell lung cancer (SCLC) who had failed two or more prior lines of treatment. With a median follow-up of 10.6 months, an intention-to-treat analysis that included 100 patients at the selected 10 mg dose, tarlatamab demonstrated an objective response rate (ORR; primary endpoint) of 40%. For key secondary endpoints, median progression-free survival (mPFS) was 4.9 months and median overall survival (mOS) was 14.3 months. There were no new safety signals observed compared to the Phase 1 study.

LUMAKRAS/LUMYKRAS

On October 5, 2023, the FDA convened an Oncologic Drugs Advisory Committee (ODAC) to discuss whether the LUMAKRAS CodeBreaK 200 study could be considered an adequate and well-controlled trial as part of the FDA's evaluation of whether this data supports the conversion of LUMAKRAS' accelerated approval for the treatment of non-small cell lung cancer (NSCLC) to a full approval. Upon review, a majority of the ODAC committee members voted that the CodeBreaK 200 primary endpoint (progression-free survival (PFS) per the blinded independent central review) could not be reliably interpreted. Regulatory review by the FDA is currently ongoing, and while we cannot speculate on the actions of the FDA and subsequent impact to LUMAKRAS, we will continue to work closely with the FDA on the full approval pathway for this important medicine. See Part II, Item 1A. Risk Factors—*Our current products and products in development cannot be sold without regulatory approval*, of this Quarterly Report.

On October 22, 2023, we announced data from the global Phase 3 CodeBreaK 300 trial evaluating two doses of LUMAKRAS/LUMYKRAS (960 mg or 240 mg) in combination with Vectibix. Both doses demonstrated a statistically significant superiority in PFS over the investigator's choice of therapy in patients with chemorefractory G12C-mutated metastatic colorectal cancer (mCRC). After a median follow-up of 7.8 months, the median PFS was 5.6 months and 3.9 months with LUMAKRAS/LUMYKRAS 960 mg plus Vectibix and LUMAKRAS/LUMYKRAS 240 mg plus Vectibix, respectively, versus 2.2 months with investigator's choice of therapy (trifluridine and tipiracil, or regorafenib). Patients at both dose regimens of LUMAKRAS/LUMYKRAS plus Vectibix experienced a longer duration of treatment than those treated with investigator's choice therapy.

Selected financial information

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
Product sales						
U.S.	$ 4,691	$ 4,466	5 %	$ 13,402	$ 12,949	3 %
ROW	1,857	1,771	5 %	5,675	5,300	7 %
Total product sales	6,548	6,237	5 %	19,077	18,249	5 %
Other revenues	355	415	(14)%	917	1,235	(26)%
Total revenues	$ 6,903	$ 6,652	4 %	$ 19,994	$ 19,484	3 %
Operating expenses	$ 4,882	$ 3,992	22 %	$ 13,368	$ 12,148	10 %
Operating income	$ 2,021	$ 2,660	(24)%	$ 6,626	$ 7,336	(10)%
Net income	$ 1,730	$ 2,143	(19)%	$ 5,950	$ 4,936	21 %
Diluted EPS	$ 3.22	$ 3.98	(19)%	$ 11.06	$ 9.11	21 %
Diluted shares	538	538	— %	538	542	(1)%

In the following discussion of changes in product sales, any reference to unit demand growth or decline refers to changes in 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) as may be noted.

Total product sales increased for the three months ended September 30, 2023, driven by volume growth for certain brands, including Repatha, Nplate, TEZSPIRE, EVENITY, BLINCYTO and Prolia, partially offset by declines in net selling prices of certain other products, including Neulasta, MVASI and Repatha, and unfavorable changes to estimated sales deductions, including for ENBREL, Neulasta, Otezla and LUMAKRAS/LUMYKRAS.

Total product sales increased for the nine months ended September 30, 2023, primarily driven by volume growth for certain brands, including Repatha, TEZSPIRE, EVENITY, Nplate, Prolia and BLINCYTO, partially offset by declines in net selling prices of certain other products, including Neulasta, MVASI, KANJINTI, Otezla, ENBREL and Repatha, unfavorable changes to estimated sales deductions, including for ENBREL, Prolia and LUMAKRAS/LUMYKRAS, and unfavorable changes to foreign currency exchange rates. For the remainder of 2023, we expect that net selling price will continue to decline year-over-year at a portfolio level, driven by increased competition.

As a result of uncertain macroeconomic conditions and geopolitical conflicts, we expect continued volatility around foreign currency exchange rates. The impact of unfavorable changes to foreign currency exchange rates will be partially offset by corresponding decreases in our international operating expenses. While not designed to completely address foreign currency changes, our hedging activities also seek to offset, in part, such effects on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros.

Our product sales were affected by reduced demand as a result of the COVID-19 pandemic, and the cumulative decrease in diagnoses over the course of the pandemic suppressed the volume of new patients starting treatment, which continues to impact the business. Given the unpredictable nature of the pandemic, there could be future intermittent disruptions in physician–patient interactions. In addition, other disruptions, including uncertain macroeconomic conditions, changes in the healthcare ecosystem and geopolitical conflicts, have the potential to introduce variability into product sales. For example, actions by governments and other entities to curb high inflation, provisions of the IRA and growth in numbers of Medicaid enrollees and uninsured individuals may have a negative impact on product sales. See Part II, Item 1A. Risk Factors, of this Quarterly Report.

Other revenues decreased for the three and nine months ended September 30, 2023, due to lower revenue from our COVID-19 manufacturing collaboration.

Operating expenses increased for the three months ended September 30, 2023, driven by a net impairment charge resulting from the termination of AMG 340, higher profit share expenses and changes in our product mix. See Note 9, Goodwill and other intangible assets, and Note 12, Fair value measurement, to the condensed consolidated financial statements.

Operating expenses increased for the nine months ended September 30, 2023, primarily driven by a net impairment charge resulting from the termination of AMG 340, changes in our product mix, higher profit share expenses, higher amortization expense from acquisition-related assets and expenses related to our restructuring plan initiated in the first quarter of 2023, partially offset by our loss on the divestiture of Gensenta in the prior period. See Note 2, Restructuring; Note 3, Acquisitions and divestitures; Note 9, Goodwill and other intangible assets; and Note 12, Fair value measurement, to the condensed consolidated financial statements.

Results of operations

Product sales

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
Prolia	$ 986	$ 862	14 %	$ 2,941	$ 2,636	12 %
ENBREL	1,035	1,106	(6)%	2,682	3,019	(11)%
XGEVA	519	495	5 %	1,585	1,530	4 %
Otezla	567	627	(10)%	1,559	1,672	(7)%
Repatha	406	309	31 %	1,218	963	26 %
Nplate	419	288	45 %	1,091	838	30 %
KYPROLIS	349	318	10 %	1,053	922	14 %
Aranesp	323	358	(10)%	1,043	1,073	(3)%
EVENITY	307	201	53 %	842	562	50 %
Other products[(1)]	1,637	1,673	(2)%	5,063	5,034	1 %
Total product sales	$ 6,548	$ 6,237	5 %	$ 19,077	$ 18,249	5 %

[(1)] Consists of product sales of our non-principal products, as well as sales in prior periods of our divested Bergamo and Gensenta subsidiaries.

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, 2022: (i) Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products; (ii) Part I, Item 1A. Risk Factors; and (iii) Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview, and Results of operations—Product sales, as well as in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2023 and June 30, 2023: (i) Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of operations—Product sales; and (ii) Part II, Item 1A. Risk Factors.

Prolia

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
Prolia — U.S.	$ 673	$ 590	14 %	$ 1,987	$ 1,783	11 %
Prolia — ROW	313	272	15 %	954	853	12 %
Total Prolia	$ 986	$ 862	14 %	$ 2,941	$ 2,636	12 %

The increase in global Prolia sales for the three and nine months ended September 30, 2023, was primarily driven by volume growth and higher net selling price.

For a discussion of litigation related to Prolia, see Part I—Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended June 30, 2023; and Note 14, Contingencies and commitments, to the condensed consolidated financial statements in this Quarterly Report.

ENBREL

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
ENBREL — U.S.	$ 1,026	$ 1,086	(6)%	$ 2,645	$ 2,965	(11)%
ENBREL — Canada	9	20	(55)%	37	54	(31)%
Total ENBREL	$ 1,035	$ 1,106	(6)%	$ 2,682	$ 3,019	(11)%

The decrease in ENBREL sales for the three months ended September 30, 2023, was primarily driven by unfavorable changes to estimated sales deductions.

The decrease in ENBREL sales for the nine months ended September 30, 2023, was driven by lower inventory, unfavorable changes to estimated sales deductions and lower net selling price.

For the remainder of 2023, we expect improved coverage will lead to growth in new patients and declining net selling price.

XGEVA

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
XGEVA — U.S.	$ 374	$ 363	3 %	$ 1,145	$ 1,122	2 %
XGEVA — ROW	145	132	10 %	440	408	8 %
Total XGEVA	$ 519	$ 495	5 %	$ 1,585	$ 1,530	4 %

The increase in global XGEVA sales for the three months ended September 30, 2023, was driven by higher net selling price.

The increase in global XGEVA sales for the nine months ended September 30, 2023, was driven by higher net selling price, partially offset by unfavorable changes to estimated sales deductions.

For a discussion of litigation related to XGEVA, see Part I—Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended June 30, 2023; and Note 14, Contingencies and commitments, to the condensed consolidated financial statements in this Quarterly Report.

Otezla

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
Otezla — U.S.	$ 462	$ 529	(13)%	$ 1,251	$ 1,366	(8)%
Otezla — ROW	105	98	7 %	308	306	1 %
Total Otezla	$ 567	$ 627	(10)%	$ 1,559	$ 1,672	(7)%

The decrease in global Otezla sales for the three months ended September 30, 2023, was driven by lower net selling price, unfavorable changes to estimated sales deductions and lower inventory, partially offset by volume growth.

The decrease in global Otezla sales for the nine months ended September 30, 2023, was driven by lower net selling price and inventory, partially offset by volume growth.

For the remainder of 2023, we expect demand to be affected by free drug programs from newly launched competition.

For a discussion of litigation related to Otezla, see Part IV—Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022; and Part I—Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2023.

Repatha

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
Repatha — U.S.	$ 183	$ 142	29 %	$ 592	$ 461	28 %
Repatha — ROW	223	167	34 %	626	502	25 %
Total Repatha	$ 406	$ 309	31 %	$ 1,218	$ 963	26 %

The increase in global Repatha sales for the three and nine months ended September 30, 2023, was driven by volume growth, partially offset by lower net selling price.

For a discussion of ongoing litigation related to Repatha, see Part IV—Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022; Part I—Note 14, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2023 and June 30, 2023; and Note 14, Contingencies and commitments, to the condensed consolidated financial statements in this Quarterly Report.

Nplate

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
Nplate — U.S.	$ 322	$ 162	99 %	$ 744	$ 474	57 %
Nplate — ROW	97	126	(23)%	347	364	(5)%
Total Nplate	$ 419	$ 288	45 %	$ 1,091	$ 838	30 %

The increase in global Nplate sales for the three and nine months ended September 30, 2023, was driven by volume growth resulting from U.S. government orders of $142 million and $224 million, respectively.

KYPROLIS

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
KYPROLIS — U.S.	$ 231	$ 217	6 %	$ 699	$ 626	12 %
KYPROLIS — ROW	118	101	17 %	354	296	20 %
Total KYPROLIS	$ 349	$ 318	10 %	$ 1,053	$ 922	14 %

The increase in global KYPROLIS sales for the three and nine months ended September 30, 2023, was primarily driven by volume growth.

Aranesp

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
Aranesp — U.S.	$ 107	$ 128	(16)%	$ 345	$ 397	(13)%
Aranesp — ROW	216	230	(6)%	698	676	3 %
Total Aranesp	$ 323	$ 358	(10)%	$ 1,043	$ 1,073	(3)%

The decrease in global Aranesp sales for the three months ended September 30, 2023, was driven by lower volume and net selling price and unfavorable changes to foreign currency exchange rates.

The decrease in global Aranesp sales for the nine months ended September 30, 2023, was driven by unfavorable changes to foreign currency exchange rates and lower net selling price, partially offset by volume growth.

U.S. Aranesp sales for the three and nine months ended September 30, 2023, decreased due to lower unit demand as a result of independent and medium-sized dialysis organizations transitioning from Aranesp to EPOGEN. We expect Aranesp to continue to face competition from EPOGEN and its biosimilars, which will impact volume and net selling price in the future.

EVENITY

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
EVENITY — U.S.	$ 214	$ 136	57 %	$ 570	$ 376	52 %
EVENITY — ROW	93	65	43 %	272	186	46 %
Total EVENITY	$ 307	$ 201	53 %	$ 842	$ 562	50 %

The increase in global EVENITY sales for the three and nine months ended September 30, 2023, was driven by volume growth.

Other products

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
Vectibix — U.S.	$ 116	$ 106	9 %	$ 345	$ 287	20 %
Vectibix — ROW	136	141	(4)%	388	368	5 %
BLINCYTO — U.S.	147	84	75 %	418	240	74 %
BLINCYTO — ROW	73	58	26 %	202	179	13 %
MVASI — U.S.	140	139	1 %	384	468	(18)%
MVASI — ROW	73	70	4 %	228	228	— %
Neulasta — U.S.	92	205	(55)%	502	772	(35)%
Neulasta — ROW	32	42	(24)%	107	133	(20)%
AMJEVITA — U.S.	23	—	NM	93	—	NM
AMGEVITA — ROW	129	117	10 %	373	341	9 %
TEZSPIRE — U.S.	161	55	*	390	91	*
Parsabiv — U.S.	59	61	(3)%	171	189	(10)%
Parsabiv — ROW	36	39	(8)%	102	100	2 %
Aimovig — U.S.	88	103	(15)%	230	289	(20)%
Aimovig — ROW	6	4	50 %	15	11	36 %
LUMAKRAS — U.S.	48	61	(21)%	146	160	(9)%
LUMYKRAS — ROW	4	14	(71)%	57	54	6 %
EPOGEN — U.S.	50	136	(63)%	171	392	(56)%
KANJINTI — U.S.	7	58	(88)%	78	207	(62)%
KANJINTI — ROW	13	14	(7)%	39	46	(15)%
TAVNEOS — U.S.	32	—	NM	84	—	NM
TAVNEOS — ROW	5	—	NM	6	—	NM
Other — U.S.[(1)]	136	105	30 %	412	284	45 %
Other — ROW[(1)]	31	61	(49)%	122	195	(37)%
Total other products	$ 1,637	$ 1,673	(2)%	$ 5,063	$ 5,034	1 %
Total U.S. — other products	$ 1,099	$ 1,113	(1)%	$ 3,424	$ 3,379	1 %
Total ROW — other products	538	560	(4)%	1,639	1,655	(1)%
Total other products	$ 1,637	$ 1,673	(2)%	$ 5,063	$ 5,034	1 %

NM = not meaningful

* Change in excess of 100%

(1) Consists of AVSOLA, Corlanor, RIABNI, NEUPOGEN, IMLYGIC, Sensipar/Mimpara and BEKEMV as well as sales in prior periods of our divested Bergamo and Gensenta subsidiaries.

Operating expenses

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

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Change	2023	2022	Change
Operating expenses:						
Cost of sales	$ 1,806	$ 1,588	14 %	$ 5,339	$ 4,659	15 %
% of product sales	27.6 %	25.5 %		28.0 %	25.5 %	
% of total revenues	26.2 %	23.9 %		26.7 %	23.9 %	
Research and development	$ 1,079	$ 1,112	(3)%	$ 3,250	$ 3,110	5 %
% of product sales	16.5 %	17.8 %		17.0 %	17.0 %	
% of total revenues	15.6 %	16.7 %		16.3 %	16.0 %	
Selling, general and administrative	$ 1,353	$ 1,287	5 %	$ 3,905	$ 3,842	2 %
% of product sales	20.7 %	20.6 %		20.5 %	21.1 %	
% of total revenues	19.6 %	19.3 %		19.5 %	19.7 %	
Other	$ 644	$ 5	*	$ 874	$ 537	63 %
Total operating expenses	$ 4,882	$ 3,992	22 %	$ 13,368	$ 12,148	10 %

* Change in excess of 100%

Cost of sales

Cost of sales increased to 26.2% and 26.7% of total revenues for the three and nine months ended September 30, 2023, respectively, primarily driven by higher profit share expenses, higher amortization expense from acquisition-related assets and changes in our product mix, partially offset by the impact of the Puerto Rico tax law change. The 2022 Puerto Rico tax law change replaced an excise tax with an income tax beginning in 2023. See Note 5, Income taxes, to the condensed consolidated financial statements.

Research and development

The decrease in R&D expense for the three months ended September 30, 2023, was driven by lower spend in research and early pipeline, partially offset by higher spend in later-stage clinical programs and marketed products.

The increase in R&D expense for the nine months ended September 30, 2023, was driven by higher spend in later-stage clinical programs and marketed products, partially offset by lower spend in research and early pipeline.

Selling, general and administrative

The increase in SG&A expense for the three and nine months ended September 30, 2023, was primarily driven by higher general and administrative expenses, including acquisition-related expenses, partially offset by lower spend for marketed products.

Other

Other operating expenses for the three and nine months ended September 30, 2023, consisted of a net impairment charge resulting from the termination of AMG 340 and expenses related to our restructuring plan initiated in the first quarter of 2023. See Note 2, Restructuring; Note 9, Goodwill and other intangible assets; and Note 12, Fair value measurement, to the condensed consolidated financial statements.

Other operating expenses for the three months ended September 30, 2022, consisted primarily of an impairment charge associated with an intangible asset acquired in a business combination. Other operating expenses for the nine months ended September 30, 2022, consisted primarily of our loss on the divestiture of Gensenta. See Note 3, Acquisitions and divestitures, to the condensed consolidated financial statements.

Nonoperating expense/income and income taxes

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Interest expense, net	$ (759)	$ (368)	$ (2,054)	$ (991)
Other income (expense), net	$ 685	$ 100	$ 2,431	$ (747)
Provision for income taxes	$ 217	$ 249	$ 1,053	$ 662
Effective tax rate	11.1 %	10.4 %	15.0 %	11.8 %

Interest expense, net

The increase in Interest expense, net, for the three and nine months ended September 30, 2023, was primarily due to higher overall debt outstanding and higher interest rates on the debt.

Other income (expense), net

During the first quarter of 2023, we changed the method of accounting for our investment in BeiGene from the equity method to recording the investment at fair value, with changes in fair value recognized in earnings. See Note 7, Investments, to the condensed consolidated financial statements.

The increase in Other income (expense), net, for the three and nine months ended September 30, 2023, was primarily due to the net gain recognized in the current year period on our investment in BeiGene and the increase in interest income due to the higher cash balance and higher interest rates.

Income taxes

The increase in our effective tax rate for the three months ended September 30, 2023, was primarily due to the Puerto Rico income tax beginning in 2023, partially offset by a prior year nondeductible loss from the divestiture of Gensenta and net earnings mix including the tax benefit from a net impairment charge related to AMG 340. See Note 9, Goodwill and other intangible assets, to the condensed consolidated financial statements. The increase in our effective tax rate for the nine months ended September 30, 2023, was primarily due to the Puerto Rico income tax beginning in 2023 and net change in earnings mix, partially offset by a prior year nondeductible loss from the divestiture of Gensenta.

The Administration and Congress continue to discuss changes to existing tax law that could substantially increase the taxes we pay to the U.S. government. Further, the OECD recently reached an agreement to align countries on a minimum corporate tax rate and an expansion of the taxing rights of market countries. Some individual jurisdictions, including the United Kingdom and some EU member countries, have begun to implement the global minimum tax agreement with effective dates as early as January 1, 2024. If enacted, either by all OECD participants or unilaterally by individual countries, this agreement could result in a tax increase that could affect our U.S. and foreign tax liabilities.

The U.S. Treasury released final foreign tax credit regulations in December 2021 that eliminated U.S. creditability of the Puerto Rico excise tax beginning in 2023. In response, on June 30, 2022, the U.S. territory of Puerto Rico enacted Act 52-2022, which provides for an alternative income tax rate on industrial development income that the U.S. Treasury confirmed will be creditable under federal law. As part of this new law, eligible businesses will be subject to incremental income and withholding taxes in lieu of payment of the Puerto Rico excise tax. In order to qualify for the alternative income tax, our current tax grant with the Puerto Rico government was amended in December 2022. We qualified for this alternative income tax beginning on January 1, 2023, and our tax expense increased. See Note 5, Income taxes, to the condensed consolidated financial statements.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010–2012, proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS appeals office but were unable to reach resolution. In July 2021, we filed a petition in the U.S. Tax Court to contest two duplicate Statutory Notices of Deficiency (Notices) for the years 2010–2012 that we received in May and July 2021, which seek to increase our U.S. taxable income for the years 2010–2012 by an amount that would result in additional federal tax of approximately $3.6 billion plus interest. Any additional tax that could be imposed for the years 2010–2012 would be reduced by up to approximately $900 million of repatriation tax previously accrued on our foreign earnings.

In 2020, we received an RAR and a modified RAR from the IRS for the years 2013–2015, 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 2010–2012. We disagreed with the proposed adjustments and calculations and pursued resolution with the IRS appeals office but were unable to reach resolution. In July 2022, we filed a petition in the U.S. Tax Court to contest a Notice for the years 2013–2015 that we previously reported receiving in April 2022 that seeks to increase our U.S. taxable income for the years 2013–2015 by an amount that would result in additional federal tax of approximately $5.1 billion, plus interest. In addition, the Notice asserts penalties of approximately $2.0 billion. Any additional tax that could be imposed for the years 2013–2015 would be reduced by up to approximately $2.2 billion of repatriation tax previously accrued on our foreign earnings.

We firmly believe that the IRS positions set forth in the 2010–2012 and 2013–2015 Notices are without merit. We are contesting the 2010–2012 and 2013–2015 Notices through the judicial process. The two cases were consolidated in the U.S. Tax Court on December 19, 2022. On February 10, 2023, the U.S. Tax Court entered an order setting a trial date of November 4, 2024.

We are currently under examination by the IRS for the years 2016–2018 with respect to issues similar to those for the 2010 through 2015 period. In addition, we are under examination by a number of 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 impact on our condensed consolidated financial statements.

We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009.

See our Annual Report on Form 10-K for the year ended December 31, 2022, Part I, Item 1A, Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability,* and Note 5, Income taxes, to the condensed consolidated financial statements in this filing for further discussion.

Financial condition, liquidity and capital resources

Selected financial data were as follows (in millions):

	September 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 34,741	$ 9,305
Total assets	$ 90,534	$ 65,121
Current portion of long-term debt	$ 1,428	$ 1,591
Long-term debt	$ 59,040	$ 37,354
Stockholders' equity	$ 7,656	$ 3,661

Cash, cash equivalents and marketable securities

Our balance of cash, cash equivalents and marketable securities was $34.7 billion as of September 30, 2023, the majority of which was used for the acquisition of Horizon. See Note 3, Acquisitions and divestitures, to the condensed consolidated financial statements. 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

Consistent with the objective to optimize our capital structure, we deploy our accumulated cash balances in a strategic manner and consider a number of alternatives, including investments in innovation both internally and externally (including investments that expand our portfolio of products in areas of therapeutic interest), capital expenditures, repayment of debt, payment of dividends and stock repurchases.

We intend to continue to invest in our business while returning capital to stockholders through the payment of cash dividends and stock repurchases, thereby reflecting our confidence in the future cash flows of our business 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 in applicable tax laws or corporate laws, changes in 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, our stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include block purchases, tender offers, ASRs and market transactions.

In August 2023, March 2023 and December 2022, our Board of Directors declared quarterly cash dividends of $2.13 per share, which were paid in September 2023, June 2023 and March 2023, respectively, and was an increase of 10% over the quarterly cash dividends paid each quarter in 2022. In October 2023, our Board of Directors declared a quarterly cash dividend of $2.13 per share that will be paid in December 2023.

During the nine months ended September 30, 2023, we did not repurchase any of our common stock. As of September 30, 2023, $7.0 billion of authorization remained available under our stock repurchase program.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of September 30, 2023 and December 31, 2022. 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 plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt markets and equity markets. See our Quarterly Report on 10-Q for the period ended March 31, 2023, Part II, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business.*

Financing arrangements

In February 2023, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time, with terms to be determined at the time of issuance. This shelf registration statement expires in February 2026.

During the three months ended March 31, 2023, in connection with the acquisition of Horizon, we issued $24.0 billion of debt composed of eight series of notes. In connection with the issue of these notes, we elected to terminate all remaining commitments under the bridge credit agreement we entered into in December 2022. In October 2023, in connection with the completion of the acquisition of Horizon, we borrowed $4.0 billion under a term loan credit agreement that we entered into in December 2022. This borrowing has an interest rate of three-month SOFR plus 1.225%, of which $2.0 billion is due in April 2025 and $2.0 billion is due in October 2026. See Note 10, Financing arrangements, to the condensed consolidated financial statements.

During the three months ended March 31, 2023, we amended and restated our syndicated, unsecured, revolving credit agreement, under which we may borrow up to $4.0 billion (increased from $2.5 billion prior to the amendment) for general corporate purposes, including as a liquidity backstop for our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $1.25 billion with the agreement of the banks (increased from $750 million prior to the amendment). Each bank that is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest for any amounts borrowed under this facility, based on our current credit rating, at (i) SOFR plus 1.01% or (ii) the highest of (A) the administrative agent bank base commercial lending rate, (B) the overnight federal funds rate plus 0.50% or (C) one-month SOFR plus 1.1%. As of September 30, 2023 and December 31, 2022, no amounts were outstanding under this facility.

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 earnings before interest, taxes, depreciation and amortization) to (ii) consolidated interest expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of September 30, 2023.

Cash flows

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

	Nine months ended September 30,	
	2023	2022
Net cash provided by operating activities	$ 7,933	$ 7,072
Net cash provided by (used in) investing activities	$ 885	$ (2,571)
Net cash provided by (used in) financing activities	$ 18,294	$ (2,988)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities during the nine months ended September 30, 2023, increased due to timing of payments to tax authorities, partially offset by lower net income after adjustments for noncash items.

Investing

Cash provided by investing activities during the nine months ended September 30, 2023, was primarily due to net cash inflows from sales and maturities of marketable securities of $1.7 billion, partially offset by capital expenditures of $863 million, including construction costs of new plants in North Carolina and Ohio. Cash used in investing activities during the nine months ended September 30, 2022, was primarily due to net cash outflows related to marketable securities activity of $1.9 billion and capital expenditures of $596 million. We currently estimate 2023 spending on capital projects to be approximately $950 million.

Financing

Cash provided by financing activities during the nine months ended September 30, 2023, was primarily due to proceeds from the issuance of debt of $23.8 billion, partially offset by the payment of dividends of $3.4 billion as well as the repayment and extinguishment of debt of $2.0 billion. Cash used in financing activities during the nine months ended September 30, 2022, was primarily due to payments to repurchase our common stock of $6.4 billion, including amounts paid under the ASR agreements, the payment of dividends of $3.2 billion and the extinguishment of debt of $297 million, partially offset by proceeds from the issuance of debt of $6.9 billion. See Note 10, Financing arrangements, and Note 11, Stockholders' equity, to the condensed consolidated financial statements for further discussion.

Critical Accounting Policies and Estimates

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 and estimates 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, 2022.

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, 2022, and is incorporated herein by reference. There were no material changes during the nine months ended September 30, 2023, 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, 2022.

During the nine months ended September 30, 2023, our outstanding debt increased by $21.5 billion, due to the issuance of $24.0 billion of debt in connection with the acquisition of Horizon. As of September 30, 2023, we had outstanding debt with a carrying value of $60.5 billion and a fair value of $56.4 billion. As of December 31, 2022, we had outstanding debt with a carrying value of $38.9 billion and a fair value of $35.0 billion. Our debt pays interest at fixed rates, and therefore changes in interest rates do not affect interest expense on our outstanding debt. Changes in interest rates would, however, affect the fair values of fixed-rate debt. A hypothetical 100 basis point decrease in interest rates relative to interest rates as of September 30, 2023 and December 31, 2022, would have resulted in an increase of $5.0 billion and $3.5 billion, respectively, in the aggregate fair value of our outstanding debt on these dates. The analysis does not consider the impact that hypothetical changes in interest rates would have on related interest rate swap contracts and cross-currency swap contracts.

Item 4. CONTROLS AND PROCEDURES

We maintain “disclosure controls and procedures,” as such term is defined under the Securities Exchange Act Rule 13a-15(e) that are designed to ensure that information required to be disclosed in Amgen’s Exchange Act reports gets recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information gets accumulated and communicated to Amgen’s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to facilitate timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen’s management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, Amgen’s management necessarily was required to apply its judgment in evaluating the cost–benefit relationship of possible controls and procedures. We carried out an evaluation under the supervision and with the participation of our management, including Amgen’s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen’s disclosure controls and procedures. Based on their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2023.

Management determined that as of September 30, 2023, no changes in our internal control over financial reporting had occurred during the fiscal quarter then ended that materially affected or are reasonably likely to materially affect our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

See Part I—Note 14, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2023, June 30, 2023 and September 30, 2023, for discussions that are limited to certain recent developments concerning our legal proceedings. Those discussions should be read in conjunction with Part IV—Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022.

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 provide in supplemental form the material changes to our risk factors that occurred during the past quarter. Our risk factors disclosed in Part I, Item 1A, of our Annual Report, on Form 10-K for the year ended December 31, 2022, provide additional disclosure for these supplemental risks and are incorporated herein by reference.

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. Further, pressures on healthcare budgets from the pandemic, the economic downturn and inflation continue and are likely to increase across the markets we serve. Payers are increasingly focused on costs, which have resulted, and are expected to continue to result, in lower reimbursement rates for our products or narrower populations for which payers will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payer dynamics, have limited, and are likely to continue to limit, our ability to set or adjust the price of our products based on their value, which can have a material adverse effect on our business. In the United States, particularly over the past few years, a number of legislative and regulatory proposals have been introduced and/or signed into law that attempt to lower drug prices. These include the IRA legislation that enables the U.S. government to set prices for certain drugs in Medicare, redesigns Medicare Part D benefits to shift a greater portion of the costs to manufacturers and enables the U.S. government to impose penalties if drug prices are increased at a rate faster than inflation. Additional proposals focused on drug pricing continue to be debated, and additional executive orders focused on drug pricing and competition are likely to be adopted and implemented in some form. Government actions or ballot initiatives at the state level also represent a highly active area of policymaking and experimentation, including pursuit of proposals that limit drug reimbursement under state run Medicaid programs based on reference prices or permitting importation of drugs from Canada. Such state policies may also eventually be adopted at the federal level.

We are unable to predict which or how many policy, regulatory, administrative or legislative changes may ultimately be, or effectively estimate the consequences to our business if, enacted and implemented. However, to the extent that payer actions 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 products, such actions could have a material adverse effect on our business and results of operations.

—Changing U.S. federal coverage and reimbursement policies and practices have affected and are likely to continue to affect access to, pricing of 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 Part I, Item 1. Business—Reimbursement, of our Annual Report on Form 10-K for the year ended December 31, 2022. Our business has been and will continue to be affected by legislative actions changing U.S. federal reimbursement policy. For example, in 2022, the IRA was enacted and includes provisions requiring that beginning in 2026, mandatory price setting be introduced in Medicare for certain drugs paid for under

Parts B and D, whereby manufacturers must accept a price established by the government or face penalties on all U.S. sales (starting with ten drugs in 2026, adding 15 in 2027 and 2028, and adding 20 in 2029 and subsequent years such that by 2031 approximately 100 drugs could be subject to such set prices). The Medicare price setting process began on August 29, 2023 when CMS announced the first ten drugs for Medicare price setting, which includes ENBREL. Our wholly owned subsidiary, Immunex Corporation, which holds the rights to the ENBREL biologics license application (BLA), entered into an agreement with the U.S. government to participate in the price setting process and submitted the required data to CMS for ENBREL, including certain price, cost and patent data. The Medicare price setting process will conclude by August 1, 2024, and on September 1, 2024, CMS will publish prices that will be applicable to these ten drugs in the Medicare program beginning January 1, 2026. Also under the IRA, starting on January 1, 2024, Medicare Part D will be redesigned to cap beneficiary out-of-pocket costs and, beginning January 1, 2025, Federal reinsurance will be reduced in the catastrophic phase (resulting in a shift and increase of such costs to Part D plans and manufacturers, including by requiring manufacturer discounts on certain drugs). Further, the IRA created a mechanism for CMS to collect rebates from manufacturers if price increases outpace inflation. Rebate obligations began to accrue October 1, 2022 for Medicare Part B and January 1, 2023 for Medicare Part D, but CMS has not yet issued invoices and has some discretion as to when it must bill manufacturers. We expect that certain of our products will be subject to these inflation rebates, and several of our products have been on lists that are issued and updated on a quarterly basis by CMS under a related program under which Medicare beneficiaries are charged reduced coinsurance if price increases exceed inflation. The IRA's drug pricing controls and Medicare redesign are likely to have a material adverse effect on our sales, our business and our results of operations, and such impact is expected to increase through the end of the decade and will depend on factors including the extent of our portfolio's exposure to Medicare reimbursement, the rate of inflation over time, the number of our products selected for mandatory price setting and the timing of market entry of generic or biosimilar competition. Further, following the passage of the IRA, the environment remains dynamic and U.S. policymakers continue to demonstrate interest in health care and drug pricing reform. For example, CMS issued a proposed Medicaid Drug Rebate Program rule that, if finalized, would require manufacturers to aggregate or "stack" all rebates, discounts, or other price concessions made to separate, unrelated entities across the pharmaceutical supply chain on a given unit of product to determine the "Best Price," a metric that is used to determine Medicaid rebates and 340B statutory rates. In early 2023, the HHS selected new healthcare payment and delivery models for testing, in response to an October 2022 Executive Order on Lowering Prescription Drug Costs for Americans, including the Accelerating Clinical Evidence Model, which could introduce new payment methods that reduce reimbursement for drugs approved under accelerated approval. That Executive Order followed a 2021 Executive Order designed to increase competition in the healthcare sector, including by calling for the FDA to develop prescription drug importation programs and the FTC to apply greater scrutiny of anticompetitive activity and responses to which include actions from the HHS (which released a report with drug pricing proposals that seek to promote competition) and from the U.S. Patent and Trademark Office (which has taken steps to strengthen coordination with the FDA to address impediments to generic drug and biosimilar competition). Other CMS policy changes and demonstration projects to test new care, delivery and payment models can also significantly affect how drugs, including our products, are covered and reimbursed. In the fourth quarter of 2021, HHS released a plan to address drug pricing that included potential future mandatory models that link payment for prescription drugs and biologics to certain factors, including the overall cost of care. In March 2023, the Administration released its budget plan for fiscal year 2024 that included proposals to expand the number of drugs subject to mandatory Medicare price setting under the IRA, imposing such price setting activity earlier, and extending to commercial health insurance the requirement that drug manufacturers pay rebates if price increases outpace inflation. While those proposed expansions of the IRA's drug pricing controls and Medicare redesigns have not been enacted, the proposals demonstrate that this area continues to be a focus of the Administration.

We also face risks related to the reporting of pricing data that affects reimbursement of and discounts provided for our products. U.S. government price reporting regulations are complex and may require biopharmaceutical manufacturers 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 may be required to pay additional rebates and provide additional discounts.

—Changing reimbursement and pricing actions in various states have negatively affected and may continue to negatively affect access to and have affected and may continue to affect sales of our products

At the state level, government actions or ballot initiatives can also affect how our products are covered and reimbursed and/or create additional pressure on our pricing decisions. Existing and proposed state pricing laws have added complexity to the pricing of drugs and may already be affecting industry pricing decisions. A number of states have adopted, and many other states are considering, drug importation programs and other pricing actions, including proposals designed to require biopharmaceutical manufacturers to report to the state proprietary pricing information or provide advance notice of certain price increases. States are also enacting laws modeled on federal policies, such as the IRA and the 340B Drug Pricing Program. For example, bills were introduced in 15 states in 2023 with provisions directed at manufacturers participating in 340B, including restricting a manufacturer's ability to direct drugs in 340B channels, recognizing 340B contract pharmacies and a prohibition on

requiring the inclusion of 340B claims modifiers. Further, following the passage of the IRA, laws have been proposed in Connecticut, Maine, Nevada, New York, Rhode Island and Virginia that would apply the drug price caps set by HHS for Medicare to all state drug prices. For Medicaid patients, states have established a Medicaid drug spending cap (New York) and implemented a new review and supplemental rebate negotiation process (Massachusetts). Seven states (Colorado, Maine, New Hampshire, Maryland, Minnesota, Oregon and Washington) have enacted laws that establish Prescription Drug Affordability Boards (PDABs) to study drug prices and identify drugs that pose affordability challenges, and in four states (Colorado, Maryland, Minnesota and Washington) include authority for the state PDAB to set upper payment limits on certain drugs in state regulated plans and, in Minnesota, upper billing limits by in-state payers and providers. States with enacted PDAB laws are in various phases of implementation, with Colorado's PDAB being the furthest along. In August 2023, the Colorado PDAB announced the first five drugs to undergo an affordability review, that includes ENBREL. If the PDAB process finds that ENBREL is unaffordable, ENBREL could be subject to an upper payment limit by as early as September 2024. Additionally, Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont have enacted laws, and several other states have proposed bills, to implement importation of drugs from Canada. The FDA has met with representatives from Colorado, Florida, Maine and New Mexico to discuss those states' proposed importation programs, and the FDA may be working towards approving such plans. Other states could adopt similar approaches or could pursue different policy changes in a continuing effort to reduce their costs. Ultimately, as with U.S. federal government actions, existing or future state government actions or ballot initiatives may also have a material adverse effect on our product sales, business and results of operations.

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

Payers, including healthcare insurers, PBMs, integrated healthcare delivery systems (vertically-integrated organizations built from consolidations of healthcare insurers and PBMs) and group purchasing organizations, increasingly seek ways to reduce their costs. With increasing frequency, payers are adopting benefit plan changes that shift a greater proportion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient co-pay or coinsurance obligations and more significant limitations on patients' use of manufacturer commercial co-pay assistance programs. Further, government regulation of payers may affect these trends. For example, CMS finalized a policy for plan years starting on or after January 1, 2021 that has caused commercial payers to more widely adopt co-pay accumulator adjustment programs. On September 29, 2023, the U.S. District Court for the District of Columbia struck down this policy, but did not require that manufacturer patient assistance be counted toward a patient's annual deductible or out-of-pocket maximum. Payers, including PBMs, have sought, and continue to seek, price discounts or rebates in connection with the placement of our products on their formularies or those they manage, and to also impose restrictions on access to or usage of our products (such as Step Therapy), require that patients receive the payer's prior authorization before covering the product, and/or chosen to exclude certain indications for which our products are approved. For example, some payers require physicians to demonstrate or document that the patients for whom Repatha has been prescribed meet their utilization criteria, and these requirements have served to limit and may continue to limit patient access to Repatha treatment. In an effort to reduce barriers to access, we reduced the net price of Repatha by providing greater discounts and rebates to payers (including PBMs that administer Medicare Part D prescription drug plans), and in response to a very high percentage of Medicare patients abandoning their Repatha prescriptions rather than paying their co-pay, we introduced a set of new National Drug Codes to make Repatha available at a lower list price. However, affordability of patient out-of-pocket co-pay cost has limited and may continue to limit patient use. Further, despite these net and list price reductions, some payers have restricted, and may continue to restrict, patient access and may seek further discounts or rebates or take other actions, such as changing formulary coverage for Repatha, that could reduce our sales of Repatha. These factors have limited, and may continue to limit, patient affordability and use, negatively affecting Repatha sales.

Further, significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs, which places greater pressure on pricing and usage negotiations with biopharmaceutical manufacturers, significantly increasing discount and rebate requirements and limiting patient access and usage. For example, in the United States, as of the beginning of 2023, the top five integrated health plans and PBMs controlled about 92% of all pharmacy prescriptions. This high degree of consolidation among insurers, PBMs and other payers, including integrated healthcare delivery systems and/or with specialty or mail-order pharmacies and pharmacy retailers, has increased the negotiating leverage such entities have over us and other biopharmaceutical manufacturers and has resulted in greater price discounts, rebates and service fees realized by those payers from our business. Each of CVS, Express Scripts and United Health Group (among the top five integrated health plans and PBMs), have Rebate Management Organizations that further increase their leverage to negotiate deeper discounts. Ultimately, additional discounts, rebates, fees, coverage changes, plan changes, restrictions or exclusions imposed by these commercial payers could have a material adverse effect on our product sales, business and results of operations. Policy reforms advanced by Congress or the Administration that refine the role of PBMs in the U.S. marketplace could have downstream implications or consequences for our business and how we interact with these entities. For example, in June 2022, the FTC launched an inquiry into the business practices of PBMs and subsequently expanded the investigation to the three rebate management organizations owned by the three largest PBMs. In addition, multiple Congressional Committees are investigating PBM practices and have also proposed legislation that could increase transparency and reporting of these practices and/or impact rebates and service

fees. The results of such inquiry could have an effect on manufacturer interactions with PBMs, resulting in changes to access for certain medicines. See our Annual Report on Form 10-K for the year ended December 31, 2022, Part I, Item 1A. Risk Factors—*Concentration of sales at certain of our wholesaler distributors and consolidation of private payers may negatively affect our business.*

Our business is also affected by policies implemented by private healthcare entities that process Medicare claims, including Medicare Administrative Contractors. For example, in the second quarter of 2022, several Medicare Administrative Contractors issued notice that TEZSPIRE would be added to their "self-administered drug" exclusion lists. Although the Medicare Administrative Contractors subsequently removed TEZSPIRE from their exclusion lists, these exclusions, if reintroduced and/or implemented, would result in Medicare beneficiaries with severe asthma losing access to TEZSPIRE coverage under Medicare Part B and potentially also under Medicare Advantage.

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

Outside the United States, we expect countries will also continue to take actions to reduce their drug expenditures and to reduce intellectual property protections. See Part I, Item 1. Business—Reimbursement, of our Annual Report on Form 10-K for the year ended December 31, 2022. Pressures to decrease drug expenditures may further intensify as the COVID-19 pandemic has strained government budgets and as economic conditions continue to worsen in certain regions, including in Europe where high inflation and the energy crisis relating to the Russia–Ukraine conflict are challenging the economies in that region. International reference pricing has been widely used by many countries outside the United States to control costs based on an external benchmark of a product's price in other countries. International reference pricing policies can change quickly and frequently and may not reflect differences in the burden of disease, indications, market structures or affordability differences across countries or regions. Other expenditure control practices, including but not limited to the use of revenue clawbacks, rebates and percentage caps on price increases, are used in various foreign jurisdictions as well. In addition, countries may refuse to reimburse or may restrict the reimbursed population for a product when their national health technology assessments do not consider a medicine to demonstrate sufficient clinical benefit beyond existing therapies or to meet certain cost effectiveness thresholds. For example, despite the EMA's approval of Repatha for the treatment of patients with established atherosclerotic disease, prior to 2020, the reimbursement of Repatha in France was limited to a narrower patient population (such as those with homozygous familial hypercholesterolemia (HoFH)) following a national health technology assessment. Many countries decide on reimbursement between potentially competing products through national or regional tenders that often result in one product receiving most or all of the sales in that country or region. Failure to obtain coverage and reimbursement for our products, a deterioration in their existing coverage and reimbursement or a decline in the timeliness or certainty of payment by payers to physicians and other providers has negatively affected, and may further negatively affect, the ability or willingness of healthcare providers to prescribe our products for their patients and otherwise negatively affect the use of our products or the prices we realize for them. Such changes have had, and could in the future have, a material adverse effect on our product sales, business and results of operations.

Our current products and products in development cannot be sold without regulatory approval.

Our business is subject to extensive regulation by numerous state and federal government authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in the other regions and countries in which we, or our partners and affiliates, sell to obtain approval from regulatory authorities before we manufacture, market and sell our products. Once our products are approved, the FDA and other U.S. and ex-U.S. regulatory agencies have substantial authority to require additional testing and reporting, perform inspections, change product labeling or mandate withdrawals of our products. Failure to comply with applicable regulatory requirements may subject us to administrative and/or judicially imposed sanctions or monetary penalties as well as reputational and other harms. The sanctions could include the FDA's or ex-U.S. regulatory authorities' refusals to approve pending applications, delays in obtaining or withdrawals of approvals, delays or suspensions of clinical trials, warning letters, product recalls or seizures, total or partial suspensions of our operations, injunctions, fines, civil penalties and/or criminal prosecutions.

Obtaining and maintaining regulatory approvals have been, and will continue to be, increasingly difficult, time-consuming and costly. Legislative bodies or regulatory agencies could enact new laws or regulations, change existing laws or regulations or change their interpretations of laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products or product candidates. The rate and degree of change in existing laws and regulations and regulatory expectations have accelerated in established markets, and regulatory expectations continue to evolve in emerging markets. We are unable to predict whether and when any further changes to laws or regulatory policies affecting our business could occur, such as changes to laws or regulations governing manufacturer communications concerning drug products and drug product candidates and whether such changes could have a material adverse effect on our product sales, business and results of operations. Further, we are reliant on regulators having the resources necessary to evaluate and approve our products. In the United States, a partial federal government shutdown halted the work of many federal agencies and their employees from late December 2018 through

late January 2019. A subsequent extended shutdown could result in reductions or delays of FDA's activities, including with respect to our ongoing clinical programs, our manufacturing of our products and product candidates and our product approvals.

Regulatory authorities have questioned, and may in the future question, the sufficiency for approval of the endpoints we select for our clinical trials. A number of our products and product candidates have been evaluated in clinical trials using surrogate endpoints that measure an effect that is known to correlate with an ultimate clinical benefit. For example, a therapeutic oncology product candidate may be evaluated for its ability to reduce or eliminate minimal residual disease (MRD), or to extend the length of time during and after the treatment that a patient lives without the disease worsening, measured by progression-free survival (PFS). Demonstrating that the product candidate induces MRD-negative responses or produces a statistically significant improvement in PFS does not necessarily mean that the product candidate will show a statistically significant improvement in overall survival or the time that the patients remain alive. In the cardiovascular (CV) setting, a heart disease therapeutic candidate may be evaluated for its ability to reduce low-density lipoprotein cholesterol (LDL-C) levels, as an elevated LDL-C level has been a surrogate endpoint for CV events such as death, heart attack and stroke. The use of surrogate endpoints such as PFS and LDL-C reduction, in the absence of other measures of clinical benefit, may not be sufficient for broad usage or approval even when such results are statistically significant. Regulatory authorities could also add new requirements, such as the completion of enrollment in a confirmatory study or the completion of an outcomes study or a meaningful portion of an outcomes study, as conditions for obtaining approval or obtaining an indication. For example, despite demonstrating that Repatha reduced LDL-C levels in a broad patient population, only after our large phase 3 outcomes study evaluating the ability of Repatha to prevent CV events met certain of its primary composite endpoint and key secondary composite endpoint did the FDA grant a broader approval of Repatha to reduce the risk of certain CV events. There may also be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to other existing treatment options can be shown. The imposition of additional requirements or our inability to meet them in a timely fashion, or at all, has delayed, and may in the future delay, our clinical development and regulatory filing efforts, delay or prevent us from obtaining regulatory approval for new product candidates or new indications for existing products, or prevent us from maintaining our current product labels.

Some of our products have been approved by U.S. and ex-U.S. regulatory authorities on an accelerated or conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, the FDA approved LUMAKRAS under accelerated approval for the treatment of adult patients with KRAS G12C-mutated local advanced or metastatic non-small cell lung cancer (NSCLC). In March 2023, we completed submission of the LUMAKRAS/LUMYKRAS CodeBreaK 200 Phase 3 confirmatory data, along with data from a Phase 2 dose comparison substudy, to the FDA and EMA. Continued approval for this indication is contingent upon the pending verification and description of clinical benefit in the submitted trial data, including an investigation, based on the data from the FDA required post-marketing trial, of whether a lower dose has a similar clinical effect to the results demonstrated in our pre-marketing trial. Regulatory authorities are placing greater focus on whether the sponsors of products originally approved on an accelerated or conditional basis have met the conditions of the accelerated or conditional approvals. If we are unable to fulfill the regulators' requirements that were conditions of a product's accelerated or conditional approval and/or if regulators reevaluate the data or risk-benefit profile of our product, the conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change the product's labeled indications, conduct an additional confirmatory clinical trial, or even withdraw the product from the market.

Regulatory authorities can also impose post-marketing pediatric study requirements. Failure to fulfill such requirements may result in regulatory or enforcement action, including financial penalties or the invalidation of a product's marketing authorization.

Safety problems or signals can arise as our products and product candidates are evaluated in clinical trials, including investigator sponsored studies, or as our marketed products are used in clinical practice. We are required continuously to collect and assess adverse events reported to us and to communicate to regulatory agencies these adverse events and safety signals regarding our products. Regulatory agencies periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. In the United States, for our products with approved Risk Evaluation and Mitigation Strategies (REMS, see our Annual Report on Form 10-K for the year ended December 31, 2022, Part I, Item 1. Business—Government Regulation—Postapproval Phase), we are required to submit periodic assessment reports to the FDA to demonstrate that the goals of the REMS are being met. REMS and other risk management programs are designed to help ensure that a drug's benefits outweigh the risks and vary in the elements they contain. If the FDA is not satisfied with the results of the periodic assessment reports we submit for any of our REMS, the FDA may also modify our REMS or take other regulatory actions, such as implementing revised or restrictive labeling. The drug delivery devices approved for use in combination with our products are also subject to regulatory oversight and review for safety and malfunctions. See our Annual Report on Form 10-K for the year ended December 31, 2022, Part I, Item 1A. Risk Factors—*Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.* If regulatory agencies determine that we or other parties (including our clinical trial investigators, those operating our patient support programs or licensees of our

products) have not complied with the applicable reporting, other pharmacovigilance or other safety or quality assessment requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including fines, marketing authorization withdrawal and other penalties. Our product candidates and marketed products can also be affected by safety problems or signals occurring with respect to products that are similar to ours or that implicate an entire class of products. Further, as a result of clinical trials, including sub-analyses or meta-analyses of earlier clinical trials (a meta-analysis involves the use of various statistical methods to combine results from previous separate but related studies) performed by us or others, concerns may arise about the sufficiency of the data or studies underlying a product's approved label. Such actual or perceived safety problems or concerns can lead to:

- revised or restrictive labeling for our products, or the potential for restrictive labeling that has resulted, and may in the future result, in our decision not to commercialize a product candidate;
- requirement of risk management or minimization activities or other regulatory agency compliance actions related to the promotion and sale of our products;
- post-marketing commitments, mandated post-marketing requirements or pharmacovigilance programs for our approved products;
- product recalls of our approved products;
- required changes to the processes used in the manufacture of our products, which could increase our manufacturing costs and affect the availability of contract manufacturers we may utilize to assist in such manufacturing;
- revocation of approval for our products from the market completely, or within particular therapeutic areas or patient types;
- increased timelines or delays in being approved by the FDA or other regulatory bodies; and/or
- treatments or product candidates not being approved by regulatory bodies.

For example, after an imbalance in positively adjudicated CV serious adverse events was observed in one of the phase 3 clinical trials for EVENITY but not in another, larger phase 3 study, in April 2019 the FDA approved EVENITY for the treatment of osteoporosis in postmenopausal women at high risk for fracture, along with a post-marketing requirement. The requirement includes a five-year observational feasibility study that could be followed by a comparative safety study or trial.

In addition to our innovative products, we are working to develop and commercialize biosimilar versions of a number of products currently manufactured, marketed and sold by other pharmaceutical companies. In some markets, there is not yet a legislative or regulatory pathway for the approval of biosimilars. In the United States, the Biologics Price Competition and Innovation Act (BPCIA) provided for such a pathway. Discussions within the FDA and other regulatory authorities, and between regulatory authorities and sponsors, continue as to the evidence needed to demonstrate biosimilarity or interchangeability for specific products. See our Annual Report on Form 10-K for the year ended December 31, 2022, Part I, Item 1A. Risk Factors—*We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.* Delays or uncertainties in the development or implementation of such pathways, or changes in existing regulatory pathways, including degradation of regulatory standards, could result in delays or difficulties in getting our biosimilar products approved by regulatory authorities, subject us to unanticipated development costs or otherwise reduce the value of the investments we have made in the biosimilars area. Further, we cannot predict the extent to which any potential legislative or policy initiatives would affect the biosimilar pathway or have a material adverse effect on our development of biosimilars, on our marketed biosimilars or on our pursuit of interchangeability designations for any biosimilar. In addition, if we are unable to bring our biosimilar products to market on a timely basis and secure "first-to-market" or other advantageous positions, our future biosimilar sales, business and results of operations could be materially and adversely affected.

Our efforts to collaborate with or acquire other companies, products, or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.

We seek innovation through significant investment in both internal R&D and external transactions, including collaborations, partnerships, alliances, licenses, joint ventures, mergers and acquisitions (collectively, acquisition activity). Acquisition activities may be subject to regulatory approvals or other requirements that are not within our control. Antitrust scrutiny by regulatory agencies and changes to regulatory approval process in the U.S. and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. There can be no assurance that such regulatory or other approvals will be obtained or that all closing conditions

required in connection with our acquisition activities will be satisfied or waived, which could result in us being unable to complete the planned acquisition activities.

Acquisition activities are complex, time consuming and expensive and may result in unanticipated costs, delays or other operational or financial problems related to integrating the acquired company and business with our company, which may divert our management's attention from other business issues and opportunities and restrict the full realization of the anticipated benefits of such transactions within the expected timeframe or at all. We may pay substantial amounts of cash, incur debt or issue equity securities to pay for acquisition activities, which could adversely affect our liquidity or result in dilution to our stockholders, respectively. For example, the funds received from our $24 billion of senior notes issued on March 2, 2023, together with our $4 billion term loan facility, have been our primary sources of payment for the acquisition of Horizon. Further, failures or difficulties in integrating or retaining new personnel or in integrating the operations of the businesses, products or assets we acquire (including related technology, research, development and commercial operations, compliance programs, manufacturing, distribution and general business operations and procedures and ESG activities) may affect our ability to realize the benefits of the transaction and grow our business and may result in us incurring asset impairment or restructuring charges. These and other challenges may arise in connection with our acquisitions of Otezla, Five Prime Therapeutics, Inc., Teneobio, ChemoCentryx, Horizon and/or our collaborations with BeiGene and Kyowa Kirin Co., Ltd., or with other acquisition activities, which could have a material adverse effect on our business, results of operations and stock price.

We may not realize the anticipated strategic benefits of our acquisition of Horizon, including our efforts to leverage Amgen's global presence and commercial and medical capabilities in inflammation and nephrology to accelerate revenue growth of Horizon's products. Our assumptions and estimates about the future revenue growth of Horizon's products may prove to be incorrect. We may also face greater than expected challenges associated with rare disease drug development (such as challenges obtaining patients for clinical trials and/or regulatory approvals) and reimbursement (such as obtaining reimbursement of orphan drugs by public health systems). We are in the process of integrating the Horizon business into ours, including a large number of complex operational and administrative systems, to form a unified combined company, including with respect to human resources, intellectual property management, research and development activities, finance, accounting and internal control processes and systems, sales operations, product distribution, commercialization efforts, information and information security systems, compliance programs and policies and supply chain systems and third party relationships (including vendors and third party manufacturers). For example, Horizon adds more than 30 contract manufacturing organizations (CMOs) to our operations (including a CMO that produces a substantial portion of KRYSTEXXA® (pegloticase) drug substance in Israel that is affected by the current conflict in Israel and Gaza). Business integrations generally, and our integration of Horizon specifically, are complex, time consuming and expensive, and we may experience unanticipated costs, delays or other operational or financial challenges. These integration efforts may also divert our management's attention and resources away from other business operations, which may disrupt to some degree our ongoing business. Failure to successfully integrate the Horizon business into ours and/or achieve its anticipated strategic benefits may result in our incurring significant asset impairment or restructuring charges, and could have a material adverse effect on our business, results of operations and stock price.

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

During the three months ended September 30, 2023, 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	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program[1]
July 1–31	—		—	$ 6,979,263,848
August 1–31	—		—	$ 6,979,263,848
September 1–30	—		—	$ 6,979,263,848
Total	—		—	

[1] In October 2022, our Board of Directors increased the amount authorized under the repurchase program by an additional $2.4 billion.

Item 5. OTHER INFORMATION

Trading Arrangements

During the three months ended September 30, 2023, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K. The Company has established controls with respect to securities trading by its directors and officers and has permitted the use of Rule 10b5-1 trading arrangements from time to time.

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.)
2.1.1	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.)
2.1.2	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.)
2.2	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.)
2.3	Irrevocable Guarantee, dated August 25, 2019, by and between Amgen Inc. and Bristol-Myers Squibb Company. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.4	Agreement and Plan of Merger, dated July 27, 2021, by and among Amgen Inc., Teneobio, Inc., Tuxedo Merger Sub, Inc., and Fortis Advisors LLC. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential)(Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2021 on November 3, 2021 and incorporated herein by reference.)
2.5	Agreement and Plan of Merger, dated as of August 3, 2022, among ChemoCentryx, Inc., Amgen Inc. and Carnation Merger Sub, Inc. (Filed as an exhibit to Form 8-K on August 4, 2022 and incorporated herein by reference.)
2.6	Transaction Agreement, dated as of December 11, 2022, by and among Amgen Inc., Pillartree Limited and Horizon Therapeutics plc. (Filed as an exhibit to Form 8-K on December 12, 2022 and incorporated herein by reference.)
2.7	Appendix 3 to the Rule 2.7 Announcement, dated as of December 12, 2022 (Conditions Appendix). (Filed as an exhibit to Form 8-K on December 12, 2022 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.)

Exhibit No.	Description
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 form of the Company's 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 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 form of the Company's 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	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.)
4.24	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.25	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.)
4.26	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.)

Exhibit No.	Description
4.27	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.)
4.28	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.)
4.29	Officer's Certificate of Amgen Inc., dated as of August 9, 2021, including forms of the Company's 1.650% Senior Notes due 2028, 2.000% Senior Notes due 2032, 2.800% Senior Notes due 2041 and 3.000% Senior Notes due 2052. (Filed as an exhibit to Form 8-K on August 9, 2021 and incorporated herein by reference.)
4.30	Officer's Certificate of Amgen Inc., dated as of February 22, 2022, including forms of the Company's 3.000% Senior Notes due 2029, 3.350% Senior Notes due 2032, 4.200% Senior Notes due 2052 and 4.400% Senior Notes due 2062. (Filed as an exhibit to Form 8-K on February 22, 2022 and incorporated herein by reference.)
4.31	Officer's Certificate of Amgen Inc., dated as of August 18, 2022, including forms of the Company's 4.050% Senior Notes due 2029, 4.200% Senior Notes due 2033 and 4.875% Senior Notes due 2053. (Filed as an exhibit to Form 8-K on August 18, 2022 and incorporated herein by reference.)
4.32	Description of Amgen Inc.'s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934. (Filed as an exhibit to Form 10-K for the year ended December 31, 2022 on February 9, 2023 and incorporated herein by reference.)
4.33	Officer's Certificate of the Company, dated as of March 2, 2023, including forms of the Company's 5.250% Senior Notes due 2025, 5.507% Senior Notes due 2026, 5.150% Senior Notes due 2028, 5.250% Senior Notes due 2030, 5.250% Senior Notes due 2033, 5.600% Senior Notes due 2043, 5.650% Senior Notes due 2053 and 5.750% Senior Notes due 2063. (Filed as an exhibit to Form 8-K on March 2, 2023 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 and Restated on December 12, 2022.)(Filed as an exhibit to Form 10-K for the year ended December 31, 2022 on February 9, 2023 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 and Restated on December 12, 2022.)(Filed as an exhibit to Form 10-K for the year ended December 31, 2022 on February 9, 2023 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 and Reinstated on December 12, 2022.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2022 on February 9, 2023 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 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.)

Exhibit No.	Description
10.10+	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.)
10.11+	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.)
10.11.1+	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.)
10.11.2+	Second Amendment to the Amgen Inc. Supplemental Retirement Plan, 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.)
10.11.3+	Third Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 20, 2021. (Filed as an exhibit to Form 10-K for the year ended December 31, 2021 on February 16, 2022 and incorporated herein by reference.)
10.11.4+	Fourth Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 20, 2022. (Filed as an exhibit to Form 10-K for the year ended December 31, 2022 on February 9, 2023 and incorporated herein by reference.)
10.12+	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.)
10.13+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2022.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2022 on April 28, 2022 and incorporated herein by reference.)
10.14+	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.)
10.14.1+	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.)
10.14.2+	Second Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective January 1, 2020. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.14.3+	Third Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective January 1, 2022. (Filed as an exhibit to Form 10-K for the year ended December 31, 2021 on February 16, 2022 and incorporated herein by reference.)
10.15+	Aircraft Time Sharing Agreement, dated December 3, 2021, by and between Amgen Inc. and Robert A. Bradway. (Filed as an exhibit to Form 10-K for the year ended December 31, 2021 on February 16, 2022 and incorporated herein by reference.)
10.16	Term Loan Credit Agreement, dated as of December 22, 2022, by and among Amgen Inc., Citibank, N.A., as administrative agent, Bank of America, N.A., as syndication agent, Citibank, N.A., Bank of America, N.A., Goldman Sachs Bank USA and Mizuho Bank, Ltd., as lead arrangers and book runners, Goldman Sachs Bank USA and Mizuho Bank, Ltd. as documentation agents, and the other banks party thereto. (Filed as an exhibit to Form 8-K on December 22, 2022 and incorporated herein by reference.)
10.17	Third Amended and Restated Credit Agreement, dated as of March 9, 2023, 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 March 9, 2023 and incorporated herein by reference.)
10.18	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.)

Exhibit No.	Description
10.18.1	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.)
10.19	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.)
10.20	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.)
10.20.1	First Amendment to Collaboration Agreement, dated April 20, 2022, by and between Amgen Inc. and BeiGene Switzerland GmbH, and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2022 on August 5, 2022 and incorporated herein by reference.)
10.20.2	Second Amendment to Collaboration Agreement, entered into as of February 26, 2023, by and between Amgen Inc. and BeiGene Switzerland GmbH, and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2023 on April 28, 2023 and incorporated herein by reference.)
10.21	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.)
10.22	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.)
10.22.1	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.)
10.22.2	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.)
10.22.3	Amendment No. 3 to Share Purchase Agreement, dated January 30, 2023, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 8-K on January 31, 2023 and incorporated herein by reference.)
10.23	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 because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2022 on August 5, 2022 and incorporated herein by reference.)
10.23.1	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 because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2022 on August 5, 2022 and incorporated herein by reference.)
10.23.2	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.)

Exhibit No.	Description
10.23.3	Amendment No. 7 to the Collaboration Agreement, dated December 17, 2020, by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 and incorporated herein by reference.)
10.23.4	Amendment No. 8 to the Collaboration Agreement, dated November 19, 2021, 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) is the type of information that the Company treats as private or confidential.)(Filed as an exhibit to Form 10-K for the year ended December 31, 2021 on February 16, 2022 and incorporated herein by reference.)
10.24	License and Collaboration Agreement, dated June 1, 2021, by and between Amgen Inc. and Kyowa Kirin Co., Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2021 on August 4, 2021 and incorporated herein by reference.)
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

(* = filed herewith)

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

(+ = management contract or compensatory plan or arrangement)

SIGNATURES

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

Amgen Inc.
(Registrant)

Date: October 31, 2023

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.

October 31, 2023

/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.

October 31, 2023

/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 September 30, 2023 (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.

October 31, 2023

/s/ ROBERT A. BRADWAY

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

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

Certification of Chief Financial Officer

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2023 (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.

October 31, 2023

/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.