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, 2022

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 31, 2022, the registrant had 533,579,206 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
ANDA	Abbreviated New Drug Application
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.
EPS	earnings per share
FASB	Financial Accounting Standards Board
FDA	U.S. Food and Drug Administration
Fitch	Fitch Ratings, Inc.
Five Prime	Five Prime Therapeutics, 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 & Human Services
IPR&D	in-process research and development
IRA	Inflation Reduction Act of 2022
IRP	international reference pricing
IRS	Internal Revenue Service
KKC	Kyowa Kirin Co., Ltd.
LIBOR	London Interbank Offered Rate
MD&A	management’s discussion and analysis
MFN	most-favored nation
Moody’s	Moody’s Investors Service, Inc.
Neumora	Neumora Therapeutics, Inc.
OECD	Organisation for Economic Co-operation and Development
PBM	pharmacy benefit manager
PDAB	Prescription Drug Affordability Board
PTAB	Patent Trial and Appeal Board
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
Teneobio	Teneobio, Inc.
U.S. Treasury	U.S. Department of Treasury
USPTO	U.S. Patent and Trademark Office
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)
AMGEVITA	AMGEVITA™ (adalimumab)
Aranesp	Aranesp® (darbepoetin alfa)
AVSOLA	AVSOLA® (infliximab-axxq)
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)
Onpro	Onpro®
Otezla	Otezla® (apremilast)
Parsabiv	Parsabiv® (etelcalcetide)
Prolia	Prolia® (denosumab)
Repatha	Repatha® (evolocumab)
RIABNI	RIABNI® (rituximab-arrx)
Sensipar/Mimpara	Sensipar®/Mimpara™ (cinacalcet)
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,	
	2022	2021	2022	2021
Revenues:				
Product sales	$ 6,237	$ 6,320	$ 18,249	$ 18,026
Other revenues	415	386	1,235	1,107
Total revenues	6,652	6,706	19,484	19,133
Operating expenses:				
Cost of sales	1,588	1,609	4,659	4,736
Research and development	1,112	1,422	3,110	3,471
Acquired in-process research and development	—	—	—	1,505
Selling, general and administrative	1,287	1,305	3,842	3,943
Other	5	(8)	537	143
Total operating expenses	3,992	4,328	12,148	13,798
Operating income	2,660	2,378	7,336	5,335
Other income (expense):				
Interest expense, net	(368)	(296)	(991)	(862)
Other income (expense), net	100	73	(747)	97
Income before income taxes	2,392	2,155	5,598	4,570
Provision for income taxes	249	271	662	576
Net income	$ 2,143	$ 1,884	$ 4,936	$ 3,994
Earnings per share:				
Basic	$ 4.01	$ 3.32	$ 9.16	$ 6.98
Diluted	$ 3.98	$ 3.31	$ 9.11	$ 6.93
Shares used in calculation of earnings per share:				
Basic	535	567	539	572
Diluted	538	570	542	576

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Net income	$ 2,143	$ 1,884	$ 4,936	$ 3,994
Other comprehensive income, net of reclassification adjustments and taxes:				
Foreign currency translation	(109)	(35)	(225)	(60)
Cash flow hedges	138	99	378	241
Losses on available-for-sale securities	—	(1)	—	(1)
Other	(9)	(3)	(9)	(3)
Other comprehensive income, net of reclassification adjustments and taxes	20	60	144	177
Comprehensive income	$ 2,163	$ 1,944	$ 5,080	$ 4,171

See accompanying notes.

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

	September 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,502	$ 7,989
Marketable securities	1,976	48
Trade receivables, net	5,326	4,895
Inventories	4,757	4,086
Other current assets	2,501	2,367
Total current assets	24,062	19,385
Property, plant and equipment, net	5,188	5,184
Intangible assets, net	13,266	15,182
Goodwill	14,845	14,890
Other noncurrent assets	6,339	6,524
Total assets	$ 63,700	$ 61,165
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,204	$ 1,366
Accrued liabilities	11,584	10,731
Current portion of long-term debt	1,543	87
Total current liabilities	14,331	12,184
Long-term debt	37,161	33,222
Long-term tax liabilities	5,680	6,594
Other noncurrent liabilities	2,875	2,465
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding—533.5 shares in 2022 and 558.3 shares in 2021	32,371	32,096
Accumulated deficit	(28,066)	(24,600)
Accumulated other comprehensive loss	(652)	(796)
Total stockholders' equity	3,653	6,700
Total liabilities and stockholders' equity	$ 63,700	$ 61,165

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, 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 (Note 10)	(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 (Note 10)	(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 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, 2020	578.3	$ 31,802	$ (21,408)	$ (985)	$ 9,409
Net income	—	—	1,646	—	1,646
Other comprehensive income, net of taxes	—	—	—	152	152
Dividends declared on common stock ($1.76 per share)	—	—	(1,012)	—	(1,012)
Issuance of common stock in connection with the Company's equity award programs	0.7	6	—	—	6
Stock-based compensation expense	—	57	—	—	57
Tax impact related to employee stock-based compensation expense	—	(59)	—	—	(59)
Repurchases of common stock	(3.7)	—	(865)	—	(865)
Balance as of March 31, 2021	575.3	31,806	(21,639)	(833)	9,334
Net income	—	—	464	—	464
Other comprehensive loss, net of taxes	—	—	—	(35)	(35)
Issuance of common stock in connection with the Company's equity award programs	0.8	47	—	—	47
Stock-based compensation expense	—	100	—	—	100
Tax impact related to employee stock-based compensation expense	—	(76)	—	—	(76)
Repurchases of common stock	(6.5)	—	(1,592)	—	(1,592)
Other	—	—	5	—	5
Balance as of June 30, 2021	569.6	31,877	(22,762)	(868)	8,247
Net income	—	—	1,884	—	1,884
Other comprehensive income, net of taxes	—	—	—	60	60
Dividends declared on common stock ($1.76 per share)	—	—	(1,017)	—	(1,017)
Issuance of common stock in connection with the Company's equity award programs	—	9	—	—	9
Stock-based compensation expense	—	111	—	—	111
Tax impact related to employee stock-based compensation expense	—	(8)	—	—	(8)
Repurchases of common stock	(4.6)	—	(1,069)	—	(1,069)
Balance as of September 30, 2021	565.0	$ 31,989	$ (22,964)	$ (808)	$ 8,217

See accompanying notes.

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

	Nine months ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net income	$ 4,936	$ 3,994
Depreciation, amortization and other	2,506	2,546
Deferred income taxes	(847)	(264)
Acquired in-process research and development	—	1,505
Adjustments for equity method investments	713	130
Loss on divestiture	565	—
Other items, net	236	57
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	(566)	(269)
Inventories	(651)	(215)
Other assets	166	(373)
Accounts payable	(142)	(260)
Accrued income taxes, net	(492)	(719)
Long-term tax liabilities	185	102
Other liabilities	463	219
Net cash provided by operating activities	7,072	6,453
Cash flows from investing activities:		
Purchases of marketable securities	(2,363)	(8,901)
Proceeds from sales of marketable securities	—	4,403
Proceeds from maturities of marketable securities	447	7,927
Purchases of property, plant and equipment	(596)	(593)
Cash paid for acquisitions, net of cash acquired	—	(1,639)
Other	(59)	(234)
Net cash (used in) provided by investing activities	(2,571)	963
Cash flows from financing activities:		
Net proceeds from issuance of debt	6,938	4,946
Extinguishment of debt	(297)	—
Repurchases of common stock (Note 10)	(6,360)	(3,532)
Dividends paid	(3,156)	(3,023)
Other	(113)	(104)
Net cash used in financing activities	(2,988)	(1,713)
Increase in cash and cash equivalents	1,513	5,703
Cash and cash equivalents at beginning of period	7,989	6,266
Cash and cash equivalents at end of period	$ 9,502	$ 11,969

See accompanying notes.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2022
(Unaudited)

1. Summary of significant accounting policies

Business

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

Basis of presentation

The financial information for the three and nine months ended September 30, 2022 and 2021, 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, 2021, 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, 2022 and June 30, 2022.

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 $9.2 billion and $8.8 billion as of September 30, 2022 and December 31, 2021, respectively.

Recent accounting pronouncements

In March 2020, the FASB issued a new accounting standard to ease the financial reporting burdens caused by the expected market transition from LIBOR and other interbank offered rates to alternative reference rates, commonly referred to as reference rate reform. The new standard provides temporary optional expedients and exceptions to current GAAP guidance on contract modifications and hedge accounting. Specifically, a modification to transition to an alternative reference rate is treated as an event that does not require contract remeasurement or reassessment of a previous accounting treatment. Moreover, for all types of hedging relationships, an entity is permitted to change the reference rate without having to dedesignate the hedging relationship. The standard is generally effective for all contract modifications made and hedging relationships evaluated through December 31, 2022. In January 2021, the FASB issued a new accounting standard that expanded the scope of the original March 2020 standard to include derivative instruments on discounting transactions. We do not expect the two standards to have a material impact on our consolidated financial statements.

In November 2021, the FASB issued a new accounting standard around the recognition and measurement of contract assets and contract liabilities from revenue contracts with customers acquired in a business combination. The new standard clarifies that contract assets and contract liabilities acquired in a business combination from an acquiree should initially be recognized by applying revenue recognition principles and not at fair value. The standard is effective for interim and annual periods beginning on January 1, 2023, and early adoption is permitted. The impact of this standard will depend on the facts and circumstances of future transactions.

2. Acquisitions and divestitures

Acquisition of Teneobio, Inc.

On October 19, 2021, we acquired all of the outstanding stock of Teneobio, a privately held, clinical-stage biotechnology company developing a new class of biologics called human heavy-chain antibodies, which are single-chain antibodies composed of the human heavy-chain domain. The transaction, which was accounted for as a business combination, includes Teneobio's proprietary bispecific and multispecific antibody technologies, which complement Amgen's existing antibody capabilities and bispecific T-cell engager (BiTE®) platform and will enable significant acceleration and efficiency in the discovery and development of new molecules to treat diseases across Amgen's core therapeutic areas. Upon its acquisition, Teneobio became a wholly owned subsidiary of Amgen, and its operations have been included in our condensed consolidated financial statements commencing on the acquisition date.

Measurement period adjustments for the nine months ended September 30, 2022, included changes to the purchase price allocation and total consideration, resulting in a net increase of $22 million to goodwill. The measurement period adjustments resulted primarily from valuation inputs pertaining to certain acquired assets based on facts and circumstances that existed as of the acquisition date and did not result from events subsequent to the acquisition date. These adjustments did not have a significant impact on Amgen's results of operations during the nine months ended September 30, 2022, and would not have had a significant impact on prior-period results if these 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 purchase price	$ 993
Contingent consideration	299
Total consideration	$ 1,292
Cash and cash equivalents	$ 100
In-process research and development	991
Finite-lived intangible asset – research and development technology rights	115
Finite-lived intangible assets – licensing rights	41
Goodwill	273
Other assets, net	16
Deferred tax liability	(244)
Total assets acquired, net	$ 1,292

Consideration for this transaction comprised of (i) an upfront cash payment of $993 million, which included a working-capital adjustment, and (ii) future contingent milestone payments to Teneobio's former equity holders of up to $1.6 billion in cash, based on the achievement of various development and regulatory milestones with regard to the lead asset (AMG 340, formerly TNB-585) and to various development milestones for other drug candidates. The estimated fair values of the contingent consideration obligations aggregated $299 million as of the acquisition date and were determined using a probability-weighted expected return methodology. The assumptions in this method include the probability of achieving the milestones and the expected payment dates, with such amounts discounted to present value based on our pretax cost of debt. See Note 11, Fair value measurement, for information regarding the estimated fair value of these obligations as of September 30, 2022.

The estimated fair values of acquired IPR&D assets totaled $991 million, of which $784 million relates to AMG 340, that is in a Phase 1 clinical trial for the treatment of metastatic castration-resistant prostate cancer (mCRPC), and the balance relates to four separate preclinical oncology programs. The R&D technology rights of $115 million relate to Teneobio's proprietary bispecific and multispecific antibody technologies; the amount is being amortized over 10 years by using the straight-line method. Teneobio has also licensed its technology and certain identified targets to various third parties, representing contractual agreements valued at $41 million. The estimated fair values for these intangible assets were determined 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 projected cash flows were based on certain assumptions attributable to the respective intangible asset, including estimates of future revenues and expenses, the time and resources needed to complete development and the probabilities of obtaining marketing approval from the FDA and other regulatory agencies.

A deferred tax liability of $244 million was recognized on 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 $273 million was recorded as goodwill, which is not deductible for tax purposes. The goodwill value represents expected synergies from both AMG 340 and the technologies acquired.

Acquisition of Five Prime Therapeutics, Inc.

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

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

Divestiture of Gensenta İlaç Sanayi ve Ticaret A.Ş.

On June 28, 2022, we entered into a share purchase agreement with Eczacıbaşı under which Eczacıbaşı would acquire all of our shares in Gensenta, a subsidiary in Turkey, in exchange for $135 million in cash. Net assets related to Gensenta of $76 million met the criteria to be classified as held-for-sale and did not meet the criteria to be classified as discontinued operations. The transaction closed on November 2, 2022, upon satisfaction of closing conditions, including approval from the Turkish Competition Authority. See Note 14, Subsequent events.

As of September 30, 2022, held-for-sale assets and liabilities of $94 million and $18 million were included in Other current assets and Accrued liabilities, respectively, in the Condensed Consolidated Balance Sheets. During the nine months ended September 30, 2022, we recognized a loss of $565 million recorded in Other operating expenses in the Condensed Consolidated Statements of Income, primarily due to the impact of the cumulative foreign currency translation loss, with valuation allowances to Other current assets and Accrued liabilities in the Condensed Consolidated Balance Sheets.

3. Revenues

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

Revenues were as follows (in millions):

	Three months ended September 30,					
	2022			2021		
	U.S.	ROW	Total	U.S.	ROW	Total
ENBREL	$ 1,086	$ 20	$ 1,106	$ 1,263	$ 26	$ 1,289
Prolia	590	272	862	530	273	803
Otezla	529	98	627	495	114	609
XGEVA	363	132	495	372	145	517
Aranesp	128	230	358	149	247	396
Repatha	142	167	309	139	133	272
KYPROLIS	217	101	318	198	95	293
Neulasta	205	42	247	360	55	415
Nplate	162	126	288	156	117	273
Other products[1]	1,044	583	1,627	896	557	1,453
Total product sales[2]	$ 4,466	$ 1,771	6,237	$ 4,558	$ 1,762	6,320
Other revenues			415			386
Total revenues			$ 6,652			$ 6,706

	Nine months ended September 30,					
	2022			2021		
	U.S.	ROW	Total	U.S.	ROW	Total
ENBREL	$ 2,965	$ 54	$ 3,019	$ 3,270	$ 87	$ 3,357
Prolia	1,783	853	2,636	1,569	806	2,375
Otezla	1,366	306	1,672	1,284	335	1,619
XGEVA	1,122	408	1,530	1,061	412	1,473
Aranesp	397	676	1,073	409	709	1,118
Repatha	461	502	963	421	423	844
KYPROLIS	626	296	922	547	277	824
Neulasta	772	133	905	1,215	168	1,383
Nplate	474	364	838	404	341	745
Other products[1]	2,983	1,708	4,691	2,655	1,633	4,288
Total product sales[2]	$ 12,949	$ 5,300	18,249	$ 12,835	$ 5,191	18,026
Other revenues			1,235			1,107
Total revenues			$ 19,484			$ 19,133

[1] Consists of product sales of our non-principal products, as well as our Gensenta and Bergamo subsidiaries.

[2] Hedging gains and losses, which are included in product sales, were not material for the three and nine months ended September 30, 2022 and 2021.

4. Income taxes

The effective tax rates for the three and nine months ended September 30, 2022, were 10.4% and 11.8%, respectively, compared with 12.6% for both of the corresponding periods of the prior year.

The decrease in our effective tax rate for the three months ended September 30, 2022, was primarily due to the prior year nondeductible IPR&D expense arising from the acquisition of Five Prime and net favorable items, partially offset by a nondeductible loss from a nonstrategic divestiture. The decrease in our effective tax rate for the nine months ended September 30, 2022, was primarily due to the prior year nondeductible IPR&D expense arising from the acquisition of Five Prime, partially offset by current year net unfavorable items compared to last year and a nondeductible loss from a nonstrategic divestiture. 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 2035. In addition, the Company's operations conducted in Singapore are subject to a tax incentive grant through 2034. These foreign earnings are also subject to U.S. tax at a reduced rate of 10.5%. See Note 2, Acquisitions and divestitures.

The U.S. territory of Puerto Rico imposes a 4% excise tax on the gross intercompany purchase price of goods and services from our manufacturer in Puerto Rico. We account for the excise tax as a manufacturing cost that is capitalized in Inventories and expensed in Cost of sales when the related products are sold. For U.S. income tax purposes, in 2022, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes when the excise tax is incurred.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes 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, and we filed a motion to consolidate the two periods into one case in the U.S. Tax Court.

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 have examinations by a number of state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our condensed consolidated financial statements.

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

See Part II, Item 1A, Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability* in our Quarterly Report on Form 10-Q for the period ended June 30, 2022, for further discussion.

During the three and nine months ended September 30, 2022, the gross amounts of our UTBs increased by $25 million and $120 million, respectively, as a result of tax positions taken during the current year. Substantially all of the UTBs as of September 30, 2022, if recognized, would affect our effective tax rate.

5. 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,	
	2022	2021	2022	2021
Income (Numerator):				
Net income for basic and diluted EPS	$ 2,143	$ 1,884	$ 4,936	$ 3,994
Shares (Denominator):				
Weighted-average shares for basic EPS	535	567	539	572
Effect of dilutive securities	3	3	3	4
Weighted-average shares for diluted EPS	538	570	542	576
Basic EPS	$ 4.01	$ 3.32	$ 9.16	$ 6.98
Diluted EPS	$ 3.98	$ 3.31	$ 9.11	$ 6.93

For the three and nine months ended September 30, 2022 and 2021, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

6. Investments

Available-for-sale investments

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

Types of securities as of September 30, 2022	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ —	$ —	$ —	$ —
U.S. Treasury bills	1,976	—	—	1,976
Money market mutual funds	8,945	—	—	8,945
Other short-term interest-bearing securities	—	—	—	—
Total interest-bearing securities	$ 10,921	$ —	$ —	$ 10,921

Types of securities as of December 31, 2021	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 47	$ —	$ —	$ 47
U.S. Treasury bills	1,400	—	—	1,400
Money market mutual funds	5,856	—	—	5,856
Other short-term interest-bearing securities	1	—	—	1
Total interest-bearing securities	$ 7,304	$ —	$ —	$ 7,304

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, 2022	December 31, 2021
Cash and cash equivalents	$ 8,945	$ 7,256
Marketable securities	1,976	48
Total interest-bearing securities	$ 10,921	$ 7,304

Cash and cash equivalents in the above table excludes bank account cash of $557 million and $733 million as of September 30, 2022 and December 31, 2021, respectively.

All interest-bearing securities as of September 30, 2022 and December 31, 2021, mature in one year or less.

For the three and nine months ended September 30, 2022 and 2021, 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

We held investments in equity securities with readily determinable fair values (publicly traded securities) of $385 million and $611 million as of September 30, 2022 and December 31, 2021, respectively, which are included in Other noncurrent assets in the Condensed Consolidated Balance Sheets. During the three months ended September 30, 2022 and 2021, net unrealized gains on publicly traded securities were $17 million and $135 million, respectively. During the nine months ended September 30, 2022 and 2021, net unrealized gains and losses on publicly traded securities were a $259 million net loss and a $104 million net gain, respectively. Realized gains and losses on sales of publicly traded securities for the three and nine months ended September 30, 2022 and 2021, were not material.

We held investments of $227 million and $262 million in equity securities without readily determinable fair values as of September 30, 2022 and December 31, 2021, respectively, which are included in Other noncurrent assets in the Condensed Consolidated Balance Sheets. 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 immaterial. During the three and nine months ended September 30, 2021, downward and upward adjustments were immaterial. Adjustments were based on observable price transactions.

Equity method investments

BeiGene, Ltd.

As of September 30, 2022 and December 31, 2021, we had an ownership interest in BeiGene of approximately 18.2% and 18.4%, respectively, which is included in Other noncurrent assets in the Condensed Consolidated Balance Sheets and accounted for under the equity method of accounting. We amortize the difference between the fair value of equity securities acquired and our proportionate share of the carrying value of the underlying net assets of BeiGene over the useful lives of the assets that gave rise to this basis difference. This amortization and our share of the results of operations of BeiGene are included in Other income (expense), net, in the Condensed Consolidated Statements of Income one quarter in arrears.

During the three months ended September 30, 2022 and 2021, the carrying value of our equity investment was adjusted by our share of BeiGene's net losses of $104 million and $98 million, respectively, and amortization of the basis difference of $48 million and $44 million, respectively. During the nine months ended September 30, 2022 and 2021, the carrying value of our equity investment was adjusted by our share of BeiGene's net losses of $292 million and $181 million, respectively, and amortization of the basis difference of $143 million and $128 million, respectively. As of September 30, 2022 and December 31, 2021, the carrying values of our investment in BeiGene totaled $2.3 billion and $2.8 billion, respectively, and the fair values of our investment totaled $2.6 billion and $5.1 billion, respectively. As of September 30, 2022, we believe the carrying value of our equity investment in BeiGene is fully recoverable.

Neumora Therapeutics, Inc.

On September 30, 2021, we acquired an approximately 25.9% ownership interest in Neumora, a privately held company, for $257 million, which is included in Other noncurrent assets in the Condensed Consolidated Balance Sheets, in exchange for a $100 million cash payment and $157 million in noncash consideration primarily related to future services. Although our equity investment provides us with the ability to exercise significant influence over Neumora, we have elected the fair value option to account for our equity investment. Under the fair value option, changes in the fair value of the investment are recognized through earnings each reporting period. We believe the fair value option best reflects the economics of the underlying transaction. During the three months ended September 30, 2022, we made an additional $10 million cash investment via participation in Neumora's subsequent financing round. As of September 30, 2022 and December 31, 2021, our ownership interest in Neumora was approximately 24.9% and 25.9%, respectively, and the fair values of our investment were $382 million and $220 million, respectively. Accordingly, for the increases in fair value of our investment during the three and nine months ended September 30, 2022, we recognized net gains of $240 million and $152 million, respectively, in Other income (expense), net, in the Condensed Consolidated Statements of Income. For information on determination of fair values, see Note 11, Fair value measurement.

Limited partnerships

We held limited partnership investments of $262 million and $573 million as of September 30, 2022 and December 31, 2021, 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, 2022, unfunded additional commitments to be made for these investments during the next several years were $189 million. For the three months ended September 30, 2022 and 2021, net unrealized losses from our limited partnership investments were $62 million and $43 million, respectively. For the nine months ended September 30, 2022 and 2021, net unrealized gains and losses from our limited partnership investments were a $282 million net loss and a $122 million net gain, respectively.

7. Inventories

Inventories consisted of the following (in millions):

	September 30, 2022	December 31, 2021
Raw materials	$ 801	$ 647
Work in process	2,929	2,367
Finished goods	1,027	1,072
Total inventories	$ 4,757	$ 4,086

8. Goodwill and other intangible assets

Goodwill

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

	Nine months ended September 30, 2022
Beginning balance	$ 14,890
Adjustments to goodwill resulting from acquisitions and divestitures, net[(1)]	6
Currency translation adjustment	(51)
Ending balance	$ 14,845

[(1)] Consists of adjustments to goodwill resulting from changes to the acquisition date fair values of net assets acquired in the acquisition of Teneobio and the nonstrategic Gensenta divestiture. See Note 2, Acquisitions and divestitures.

Other intangible assets

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

	September 30, 2022			December 31, 2021		
	Gross carrying amounts	Accumulated amortization	Other intangible assets, net	Gross carrying amounts	Accumulated amortization	Other intangible assets, net
Finite-lived intangible assets:						
Developed-product-technology rights	$ 25,504	$ (14,396)	$ 11,108	$ 25,561	$ (12,769)	$ 12,792
Licensing rights	3,864	(3,087)	777	3,807	(2,973)	834
Marketing-related rights	1,326	(1,146)	180	1,354	(1,112)	242
Research and development technology rights	1,334	(1,142)	192	1,377	(1,133)	244
Total finite-lived intangible assets	32,028	(19,771)	12,257	32,099	(17,987)	14,112
Indefinite-lived intangible assets:						
In-process research and development	1,009	—	1,009	1,070	—	1,070
Total other intangible assets	$ 33,037	$ (19,771)	$ 13,266	$ 33,169	$ (17,987)	$ 15,182

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, 2022 and 2021, we recognized amortization associated with our finite-lived intangible assets of $628 million and $642 million, respectively. During the nine months ended September 30, 2022 and 2021, we recognized amortization associated with our finite-lived intangible assets of $1.9 billion in both periods. Amortization of intangible assets is primarily included in Cost of sales in the Condensed Consolidated Statements of Income. The total estimated amortization for our finite-lived intangible assets for the remaining three months ending December 31, 2022, and the years ending December 31, 2023, 2024, 2025, 2026 and 2027, are $0.6 billion, $2.5 billion, $2.4 billion, $2.2 billion, $1.8 billion and $1.8 billion, respectively.

9. Financing arrangements

Our borrowings consisted of the following (in millions):

	September 30, 2022	December 31, 2021
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	$ 709	$ 767
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
1.90% notes due 2025 (1.90% 2025 Notes)	500	500
3.125% notes due 2025 (3.125% 2025 Notes)	1,000	1,000
2.00% €750 million notes due 2026 (2.00% 2026 euro Notes)	735	853
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)	531	643
2.20% notes due 2027 (2.20% 2027 Notes)	1,724	1,750
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
1.65% notes due 2028 (1.65% 2028 Notes)	1,234	1,250
3.00% notes due 2029 (3.00% 2029 Notes)	750	—
4.05% notes due 2029 (4.05% 2029 Notes)	1,250	—
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	782	947
2.45% notes due 2030 (2.45% 2030 Notes)	1,250	1,250
2.30% notes due 2031 (2.30% 2031 Notes)	1,250	1,250
2.00% notes due 2032 (2.00% 2032 Notes)	1,051	1,250
3.35% notes due 2032 (3.35% 2032 Notes)	1,000	—
4.20% notes due 2033 (4.20% 2033 Notes)	750	—
6.375% notes due 2037 (6.375% 2037 Notes)	478	478
6.90% notes due 2038 (6.90% 2038 Notes)	254	254
6.40% notes due 2039 (6.40% 2039 Notes)	333	333
3.15% notes due 2040 (3.15% 2040 Notes)	2,000	2,000
5.75% notes due 2040 (5.75% 2040 Notes)	373	373
2.80% notes due 2041 (2.80% 2041 Notes)	1,110	1,150
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	729	729
5.65% notes due 2042 (5.65% 2042 Notes)	415	415
5.375% notes due 2043 (5.375% 2043 Notes)	185	185
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415
3.375% notes due 2050 (3.375% 2050 Notes)	2,250	2,250
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
3.00% notes due 2052 (3.00% 2052 Notes)	1,254	1,350
4.20% notes due 2052 (4.20% 2052 Notes)	1,000	—
4.875% notes due 2053 (4.875% 2053 Notes)	1,000	—
2.77% notes due 2053 (2.77% 2053 Notes)	940	940
4.40% notes due 2062 (4.40% 2062 Notes)	1,250	—
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(1,252)	(1,213)
Fair value adjustments	(450)	284
Other	13	15
Total carrying value of debt	38,704	33,309
Less current portion	(1,543)	(87)
Total long-term debt	$ 37,161	$ 33,222

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

During the three months ended March 31, 2022, we issued $4.0 billion of debt consisting of $750 million of the 3.00% 2029 Notes, $1.0 billion of the 3.35% 2032 Notes, $1.0 billion of the 4.20% 2052 Notes and $1.25 billion of the 4.40% 2062 Notes. The 3.00% 2029 Notes were issued to finance eligible projects that meet specified criteria to benefit the environment. In the event of a change-in-control triggering event, as defined in the terms of the notes, we may be required to purchase all or a portion of these notes at a price equal to 101% of the principal amount of the notes plus accrued and unpaid interest. In addition, these notes may be redeemed at any time at our option, in whole or in part, at the principal amount of the notes being redeemed plus accrued and unpaid interest and a make-whole amount, which are defined by the terms of the notes. The notes may be redeemed without payment of make-whole amounts if redemption occurs during a specified period of time immediately prior to the maturing of the notes. Such time periods range from two months to six months prior to maturity.

During the three months ended September 30, 2022, we issued $3.0 billion of debt consisting of $1.25 billion of the 4.05% 2029 Notes, $750 million of the 4.20% 2033 Notes and $1.0 billion of the 4.875% 2053 Notes. In the event of a change-in-control triggering event, as defined in the terms of the notes, we may be required to purchase all or a portion of these notes at a price equal to 101% of the principal amount of the notes plus accrued and unpaid interest. In addition, these notes may be redeemed at any time at our option, in whole or in part, at the principal amount of the notes being redeemed plus accrued and unpaid interest and a make-whole amount, which are defined by the terms of the notes. The notes may be redeemed without payment of make-whole amounts if redemption occurs during a specified period of time immediately prior to the maturing of the notes. Such time periods range from two months to six months prior to maturity.

Debt extinguishment

During the three months ended September 30, 2022, we repurchased portions of the 2.20% 2027 Notes, the 1.65% 2028 Notes, the 2.00% 2032 Notes, the 2.80% 2041 Notes and the 3.00% 2052 Notes for an aggregate cost of $297 million, which resulted in the recognition of a $78 million gain on extinguishment of debt recorded in Other income (expense), net, in the Condensed Consolidated Statements of Income.

10. Stockholders' equity

Stock repurchase program

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

	2022		2021	
	Shares	Dollars	Shares	Dollars
First quarter	24.6	$ 5,410	3.7	$ 865
Second quarter	—	—	6.5	1,592
Third quarter	1.5	900	4.6	1,069
Total stock repurchases	26.1	$ 6,310	14.8	$ 3,526

On February 24, 2022, the Company entered into ASR agreements with three third-party financial institutions (Dealers). Under the ASR agreements, the Company made payments in an aggregate amount of $6.0 billion on February 25, 2022, to the Dealers and received and retired an initial 23.3 million shares of the Company's common stock from the Dealers. The payments were recorded as reductions to shareholders' equity, consisting of a $5.1 billion increase to accumulated deficit, which reflects the value of the initial shares received, and a $0.9 billion decrease in additional paid-in capital, which reflects the value of the stock that remained to be delivered by the Dealers. During the third quarter of 2022, an additional 1.5 million shares of the Company's common stock were received from the Dealers which constituted final settlement under the ASR agreements, and accordingly, the $0.9 billion decrease in additional paid-in capital recorded in February was reclassified to accumulated deficit. In total, we repurchased 26.1 million shares of common stock during the nine months ended September 30, 2022, consisting primarily of the 24.8 million shares received under the ASR agreements.

As of September 30, 2022, $4.6 billion of authorization remained available under our stock repurchase program.

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

Dividends

In August 2022, March 2022 and December 2021, the Board of Directors declared quarterly cash dividends of $1.94 per share, which were paid in September 2022, June 2022 and March 2022, respectively. In October 2022, the Board of Directors declared a quarterly cash dividend of $1.94 per share, which will be paid in December 2022.

Accumulated other comprehensive income (loss)

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

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2021	$ (844)	$ 61	$ —	$ (13)	$ (796)
Foreign currency translation adjustments	(51)	—	—	—	(51)
Unrealized gains	—	56	—	—	56
Reclassification adjustments to income	—	51	—	—	51
Income taxes	—	(23)	—	—	(23)
Balance as of March 31, 2022	(895)	145	—	(13)	(763)
Foreign currency translation adjustments	(65)	—	—	—	(65)
Unrealized gains	—	67	—	—	67
Reclassification adjustments to income	—	132	—	—	132
Income taxes	—	(43)	—	—	(43)
Balance as of June 30, 2022	(960)	301	—	(13)	(672)
Foreign currency translation adjustments	(109)	—	—	—	(109)
Unrealized gains	—	45	—	—	45
Reclassification adjustments to income	—	129	—	—	129
Other	—	—	—	(9)	(9)
Income taxes	—	(36)	—	—	(36)
Balance as of September 30, 2022	$ (1,069)	$ 439	$ —	$ (22)	$ (652)

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	2022	2021	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract gains (losses)	$ 69	$ (5)	Product sales
Cross-currency swap contract losses	(198)	(104)	Other income (expense), net
	(129)	(109)	Income before income taxes
	28	23	Provision for income taxes
	$ (101)	$ (86)	Net income

	Nine months ended September 30,		
Components of AOCI	2022	2021	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract gains (losses)	$ 149	$ (24)	Product sales
Cross-currency swap contract losses	(461)	(190)	Other income (expense), net
	(312)	(214)	Income before income taxes
	67	45	Provision for income taxes
	$ (245)	$ (169)	Net income

11. Fair value measurement

To estimate the fair value of our financial assets and liabilities, we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing an asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about 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, 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 notes	$ —	$ —	$ —	$ —
U.S. Treasury bills	1,976	—	—	1,976
Money market mutual funds	8,945	—	—	8,945
Other short-term interest-bearing securities	—	—	—	—
Other investments	—	135	—	135
Equity securities	385	—	382	767
Derivatives:				
Foreign currency contracts	—	639	—	639
Cross-currency swap contracts	—	6	—	6
Interest rate swap contracts	—	—	—	—
Total assets	$ 11,306	$ 780	$ 382	$ 12,468
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 22	$ —	$ 22
Cross-currency swap contracts	—	754	—	754
Interest rate swap contracts	—	810	—	810
Contingent consideration obligations	—	—	302	302
Total liabilities	$ —	$ 1,586	$ 302	$ 1,888

Fair value measurement as of December 31, 2021, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	$ 47	$ —	$ —	$ 47
U.S. Treasury bills	1,400	—	—	1,400
Money market mutual funds	5,856	—	—	5,856
Other short-term interest-bearing securities	—	1	—	1
Other investments	—	—	—	—
Equity securities	611	—	220	831
Derivatives:				
Foreign currency contracts	—	183	—	183
Cross-currency swap contracts	—	66	—	66
Interest rate swap contracts	—	16	—	16
Total assets	$ 7,914	$ 266	$ 220	$ 8,400
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 39	$ —	$ 39
Cross-currency swap contracts	—	339	—	339
Interest rate swap contracts	—	156	—	156
Contingent consideration obligations	—	—	342	342
Total liabilities	$ —	$ 534	$ 342	$ 876

Interest-bearing and equity securities

The fair values of our U.S. Treasury securities, money market mutual funds and equity investments in publicly traded securities are based on quoted market prices in active markets, with no valuation adjustment. Other investments consist of interest-bearing deposits that are valued at amortized cost, which approximates fair value given their near term maturity. The fair value of equity securities without readily determinable fair values are initially valued at the transaction 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.

Derivatives

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

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency-basis swap spreads. See Note 12, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by using an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include LIBOR, swap rates and obligor credit default swap rates. See Note 12, Derivative instruments.

Contingent consideration obligations

As a result of our business acquisitions, we have incurred contingent consideration obligations 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,	
	2022	2021	2022	2021
Beginning balance	$ 310	$ 48	$ 342	$ 33
Payments	(2)	(2)	(5)	(5)
Net changes in valuations	(6)	(11)	(35)	7
Ending balance	$ 302	$ 35	$ 302	$ 35

As of September 30, 2022 and December 31, 2021, our contingent consideration obligations are primarily the result of our acquisition of Teneobio in October 2021, which obligates 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. See Note 2, Acquisitions and divestitures.

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, 2022 and December 31, 2021, the aggregate fair values of our borrowings were $34.2 billion and $37.9 billion, respectively, and the carrying values were $38.7 billion and $33.3 billion, respectively.

Investment in BeiGene, Ltd.

We estimated the fair value of our investment in BeiGene by using Level 1 inputs. As of September 30, 2022 and December 31, 2021, the fair values were $2.6 billion and $5.1 billion, and the carrying values were $2.3 billion and $2.8 billion, respectively.

During the three and nine months ended September 30, 2022 and 2021, there were no transfers of assets or liabilities between fair value measurement levels, and there were no material remeasurements to the fair values of assets and liabilities that are not measured at fair value on a recurring basis, except with respect to the impairment of net assets in connection with the nonstrategic Gensenta divestiture. See Note 2, Acquisitions and divestitures.

12. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we use or have used certain derivative instruments, including foreign currency forward, cross-currency swap, forward interest rate and interest rate swap contracts. We do not use derivatives for speculative-trading purposes.

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates primarily associated with our euro-denominated international product sales. Increases and decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are partially offset by corresponding increases and decreases in the cash flows from our international operating expenses resulting from these foreign currency exchange rate movements. To further reduce our exposure to foreign currency exchange rate fluctuations with regard to our international product sales, we enter into foreign currency forward contracts to hedge a portion of our projected international product sales up to a maximum of three years into the future; and at any given point in time, a higher percentage of nearer-term projected product sales is being hedged than in successive periods.

As of September 30, 2022 and December 31, 2021, we had outstanding foreign currency forward contracts with aggregate notional amounts of $5.5 billion and $5.7 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, 2022, were as follows (notional amounts in millions):

	Foreign currency			U.S. dollars	
Hedged notes	**Notional amounts**		**Interest rates**	**Notional amounts**	**Interest rates**
0.41% 2023 Swiss franc Bonds	CHF	700	0.4 %	$ 704	3.4 %
2.00% 2026 euro Notes	€	750	2.0 %	$ 833	3.9 %
5.50% 2026 pound sterling Notes	£	475	5.5 %	$ 747	6.0 %
4.00% 2029 pound sterling Notes	£	700	4.0 %	$ 1,111	4.6 %

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Condensed Consolidated Balance Sheets and are amortized into Interest expense, net, in the Condensed Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the nine months ended September 30, 2022, and amounts expected to be recognized during the subsequent 12 months are not material.

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

	Three months ended September 30,		Nine months ended September 30,	
Derivatives in cash flow hedging relationships	**2022**	**2021**	**2022**	**2021**
Foreign currency contracts	$ 324	$ 136	$ 654	$ 273
Cross-currency swap contracts	(279)	(120)	(486)	(180)
Total unrealized gains	$ 45	$ 16	$ 168	$ 93

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified for and were designated as fair value hedges. These interest rate swap contracts effectively convert fixed-rate coupons to floating-rate LIBOR-based coupons over the terms of the related hedge contracts. As of September 30, 2022 and December 31, 2021, 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):

	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
Condensed Consolidated Balance Sheets locations	**September 30, 2022**	**December 31, 2021**	**September 30, 2022**	**December 31, 2021**
Current portion of long-term debt	$ 82	$ 85	$ 82	$ 85
Long-term debt	$ 6,002	$ 6,729	$ (532)	$ 199

(1) Current portion of long-term debt includes $82 million and $85 million of carrying value with discontinued hedging relationships as of September 30, 2022 and December 31, 2021, respectively. Long-term debt includes $378 million and $440 million of carrying value with discontinued hedging relationships as of September 30, 2022 and December 31, 2021, respectively.

(2) Current portion of long-term debt includes $82 million and $85 million of hedging adjustments on discontinued hedging relationships as of September 30, 2022 and December 31, 2021, respectively. Long-term debt includes $278 million and $340 million of hedging adjustments on discontinued hedging relationships as of September 30, 2022 and December 31, 2021, 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, 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 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)

	Three months ended September 30, 2021			Nine months ended September 30, 2021		
	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	$ 6,320	$ 73	$ (296)	$ 18,026	$ 97	$ (862)
The effects of cash flow and fair value hedging:						
Losses on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency contracts	$ (5)	$ —	$ —	$ (24)	$ —	$ —
Cross-currency swap contracts	$ —	$ (104)	$ —	$ —	$ (190)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:						
Hedged items[1]	$ —	$ —	$ 54	$ —	$ —	$ 195
Derivatives designated as hedging instruments	$ —	$ —	$ (31)	$ —	$ —	$ (128)

[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, 2022, we expected to reclassify $304 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, 2022 and December 31, 2021, the total notional amounts of these foreign currency forward contracts were $501 million and $680 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, 2022 and 2021.

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

	Derivative assets		Derivative liabilities	
September 30, 2022	**Condensed Consolidated Balance Sheets locations**	**Fair values**	**Condensed Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other noncurrent assets	$ 639	Accrued liabilities/ Other noncurrent liabilities	$ 22
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	6	Accrued liabilities/ Other noncurrent liabilities	754
Interest rate swap contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	810
Total derivatives designated as hedging instruments		$ 645		$ 1,586

	Derivative assets		Derivative liabilities	
December 31, 2021	**Condensed Consolidated Balance Sheets locations**	**Fair values**	**Condensed Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other noncurrent assets	$ 183	Accrued liabilities/ Other noncurrent liabilities	$ 39
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	66	Accrued liabilities/ Other noncurrent liabilities	339
Interest rate swap contracts	Other current assets/ Other noncurrent assets	16	Accrued liabilities/ Other noncurrent liabilities	156
Total derivatives designated as hedging instruments		$ 265		$ 534

Our derivative contracts that were in liability positions as of September 30, 2022, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change-in-control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change-in-control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the contracts may be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

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

13. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See our Annual Report on Form 10-K for the year ended December 31, 2021, Part I, Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations*. We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote; in Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2021; and in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2022 and June 30, 2022.

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Our legal proceedings involve various aspects of our business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing; in Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2021; and in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2022 and June 30, 2022, in which we could incur a liability, our opponents seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process, which in complex proceedings of the sort we face often extend for several years. As a result, none of the matters described in this filing; in Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2021; and in Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2022 and June 30, 2022, 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. Although 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:

ANDA Patent Litigation

Otezla ANDA Patent Litigation

Amgen Inc. v. Apotex Inc.

On October 14, 2022, Apotex Inc. (Apotex) filed its answer to Amgen's complaint in the U.S. District Court for the District of New Jersey (the New Jersey District Court) in a lawsuit filed by Amgen for infringement of U.S. Patent Nos. 7,427,638, 9,872,854 and 10,092,541, which are listed in the Orange Book for Otezla. Apotex's answer disputed infringement and/or validity of the patents-in-suit. Along with its answer, Apotex also filed declaratory judgment counterclaims asserting that the patents-in-suit are not infringed and/or are invalid. Amgen's lawsuit is based on Apotex's submission of an ANDA seeking FDA approval to market a generic version of Otezla and seeks an order of the New Jersey District Court making any FDA approval of Apotex's ANDA effective no earlier than the expiration of the applicable patents.

Repatha Patent Litigation

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

On November 18, 2021, Amgen filed a petition for writ of certiorari with the U.S. Supreme Court seeking review of the invalidation of claims 19 and 29 of U.S. Patent No. 8,829,165 and claim 7 of U.S. Patent No. 8,859,741 as lacking an enabling disclosure of the invention. On April 18, 2022, the U.S. Supreme Court requested that the Office of the Solicitor General of the United States submit a brief providing the government's view on the issues raised by Amgen's petition. On September 21, 2022, the Solicitor General submitted a brief expressing the view that the U.S. Supreme Court should deny Amgen's petition for writ of certiorari.

Patent Disputes in the International Region

On August 16, 2022, the Opposition Division of the European Patent Office issued a written decision upholding the validity of the European Patent No. 2,756,004 claims at issue, with narrowing amendments. Proceedings before the Technical Board of Appeal commenced on August 17, 2022.

Antitrust Actions

Regeneron Pharmaceuticals, Inc. Antitrust Action

On August 11, 2022, Amgen moved to stay the case pending the ultimate decision on the merits of the ongoing patent litigation between Amgen and Regeneron Pharmaceuticals, Inc. in *Amgen Inc., et al. v. Sanofi, et al.* The motion to stay is scheduled for oral argument on January 6, 2023, and Amgen's motion to dismiss that was filed on August 1, 2022 is also set to be heard on that date.

U.S. Tax Litigation

Amgen Inc. & Subsidiaries v. Commissioner of Internal Revenue

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

ChemoCentryx, Inc. Securities Matters

On May 5 and June 8 of 2021, ChemoCentryx and its Chief Executive Officer were named as defendants in two putative shareholder class actions filed in the U.S. District Court for the Northern District of California (Northern District Court of California). These cases were consolidated into *Homyk v. ChemoCentryx, Inc.* in which the plaintiffs allege violations of Sections 10(b) and 20(a) of the Securities Exchange Act in connection with statements regarding the New Drug Application for TAVNEOS® (avacopan) and the underlying Phase 3 clinical trial, seeking an award of damages, interest and attorneys' fees. On March 28, 2022, the plaintiffs filed their consolidated amended complaint, and on May 19, 2022, ChemoCentryx moved to dismiss these claims.

On January 25, 2022, the Board of Directors and certain of ChemoCentryx's officers were named as defendants in a putative shareholder derivative action filed in the Northern District Court of California, *Napoli v. Schall*, and on March 11, 2022, the Northern District Court of California stayed the action until judgment is entered in the *Homyk v. ChemoCentryx, Inc.* action.

14. Subsequent events

Acquisition of ChemoCentryx, Inc.

On October 20, 2022, Amgen completed its acquisition of ChemoCentryx for $52.00 per share in cash, for an aggregate merger consideration of approximately $3.7 billion. ChemoCentryx is a biopharmaceutical company focused on orally administered therapeutics to treat autoimmune diseases, inflammatory disorders and cancer.

The accounting impact of this acquisition and the results of operations for ChemoCentryx will be included in our consolidated financial statements beginning in the fourth quarter of 2022. The initial accounting for this acquisition is incomplete, pending identification and measurement of the assets acquired and liabilities assumed.

Divestiture of Gensenta İlaç Sanayi ve Ticaret A.Ş.

On November 2, 2022, Amgen completed its divestiture transaction with Eczacıbaşı. The accounting impact upon completion of this divestiture will be included in our consolidated financial statements in the fourth quarter of 2022. See Note 2, Acquisitions and divestitures.

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, 2021, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2022 and June 30, 2022. 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, 2021, and in Part II, Item 1A. Risk Factors of our Quarterly Reports on Form 10-Q for the periods ended March 31, 2022 and June 30, 2022. We have based our forward-looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecasted by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, EPS, liquidity and capital resources, trends, planned dividends, stock repurchases, collaborations and effects of pandemics. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

Amgen is a biotechnology company committed to unlocking the potential of biology for patients suffering from serious illnesses. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Our principal products are ENBREL, Prolia, Otezla, XGEVA, Aranesp, Repatha, KYPROLIS, Neulasta and Nplate. We also market a number of other products, including MVASI, Vectibix, EVENITY, BLINCYTO, EPOGEN, AMGEVITA, Aimovig, Parsabiv, KANJINTI, LUMAKRAS/LUMYKRAS, NEUPOGEN, TEZSPIRE and Sensipar/Mimpara.

COVID-19 pandemic

Since the onset of the pandemic in 2020, we have been closely monitoring the pandemic's effects on our global operations. We continue to take appropriate steps to minimize risks to our employees, a significant number of whom have continued to work virtually. To date, our remote working arrangements have not significantly affected our ability to maintain critical business operations, and we have not experienced disruptions to or shortages of our supply of medicines.

Over the course of the pandemic we have experienced changes in demand for some of our products as fluctuations in the frequency of patient visits to doctors' offices have impacted the provision of treatments to existing patients and reduced diagnoses in new patients. During 2021, there was a gradual recovery in both patient visits and diagnosis rates that approached pre-pandemic levels. In 2022, the pandemic has continued to impact the healthcare sector and our business, to varying degrees across our markets. To date in 2022, in most of our major markets, with the exception of the Asia Pacific region that has been affected by sustained lockdowns, we have seen greater stability in patient visits and demand patterns even in areas facing surges in the virus. Given the evolution of COVID-19 since its onset, including the proliferation of variants, we cannot predict the impact of future virus surges on our business and will continue to closely monitor the impact of COVID-19 on our business and on the healthcare sector more generally.

With respect to our drug development activities, we continue to work to mitigate COVID-19 effects on future study enrollment in our clinical trials around the world. We remain focused on effectively supporting the delivery of care and investigational drug supply to patients enrolled in our active clinical sites.

Despite the ongoing pandemic and business impacts noted above, we believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital, capital expenditures and debt service requirements as well as to engage in capital-return and other business initiatives that we plan to pursue. For a discussion of risks the COVID-19 pandemic presents to our results, see Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2021, and Part II, Item 1A. Risk Factors of our Quarterly Report on Form 10-Q for the period ended March 31, 2022.

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 quarter ended June 30, 2022. 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, 2021, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2022 and June 30, 2022.

Acquisition

ChemoCentryx, Inc.

- On October 20, 2022, Amgen completed its acquisition of ChemoCentryx for $52.00 per share in cash, for an aggregate merger consideration of approximately $3.7 billion.

Products/Pipeline

Oncology/Hematology

LUMAKRAS/LUMYKRAS

- In September 2022, we announced results from the global Phase 3 CodeBreaK 200 trial, which showed once-daily oral LUMAKRAS/LUMYKRAS led to significantly superior progression-free survival (PFS; primary endpoint) and a significantly higher objective response rate (ORR; a key secondary endpoint) in patients with KRAS G12C-mutated non-small cell lung cancer (NSCLC), compared with intravenous chemotherapy, docetaxel. LUMAKRAS/LUMYKRAS significantly improved PFS compared to docetaxel in heavily pre-treated patients. The proportion of patients with PFS at one year was 25% for LUMAKRAS/LUMYKRAS versus 10% for docetaxel. LUMAKRAS/LUMYKRAS demonstrated a significantly higher ORR than docetaxel with double the response rates in the LUMAKRAS/LUMYKRAS arm (28% versus 13%, respectively).

ABP 959

- In August 2022, we announced positive top-line results from the DAHLIA study, a randomized, double-blind, active-controlled, two-period crossover Phase 3 study evaluating the efficacy and safety of ABP 959, a biosimilar candidate to SOLIRIS® (eculizumab), compared with SOLIRIS® in adult patients with paroxysmal nocturnal hemoglobinuria (PNH). The study met its primary endpoints, demonstrating no clinically meaningful differences between ABP 959 and SOLIRIS®. The safety and immunogenicity profile of ABP 959 was comparable to that of SOLIRIS®.

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,		
	2022	2021	Change	2022	2021	Change
Product sales						
U.S.	$ 4,466	$ 4,558	(2)%	$ 12,949	$ 12,835	1 %
ROW	1,771	1,762	1 %	5,300	5,191	2 %
Total product sales	6,237	6,320	(1)%	18,249	18,026	1 %
Other revenues	415	386	8 %	1,235	1,107	12 %
Total revenues	$ 6,652	$ 6,706	(1)%	$ 19,484	$ 19,133	2 %
Operating expenses	$ 3,992	$ 4,328	(8)%	$ 12,148	$ 13,798	(12)%
Operating income	$ 2,660	$ 2,378	12 %	$ 7,336	$ 5,335	38 %
Net income	$ 2,143	$ 1,884	14 %	$ 4,936	$ 3,994	24 %
Diluted EPS	$ 3.98	$ 3.31	20 %	$ 9.11	$ 6.93	31 %
Diluted shares	538	570	(6)%	542	576	(6)%

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).

Total product sales decreased for the three months ended September 30, 2022, primarily driven by declines in the net selling prices of certain products and unfavorable changes to foreign currency exchange rates, inventory and estimated sales deductions, partially offset by higher unit demand for certain brands, including Repatha, Prolia, EVENITY, Otezla, TEZSPIRE and Vectibix. Total product sales increased for the nine months ended September 30, 2022, primarily driven by higher unit demand for certain brands, including Repatha, Prolia, EVENITY, LUMAKRAS/LUMYKRAS, KYPROLIS and Otezla, partially offset by declines in the net selling prices of certain products and unfavorable changes to foreign currency exchange rates and inventory. For the remainder of 2022, we expect that net selling prices will continue to decline at a portfolio level, driven by increased competition.

Further, we expect international product sales to continue to be unfavorably impacted by foreign currency exchange rates for the remainder of the year. The impact of such 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.

Over the course of the COVID-19 pandemic we experienced changes in demand for some of our products as fluctuations in the frequency of patient visits to doctors' offices have impacted the provision of treatments to existing patients and reduced diagnoses in new patients. In general, declines in the sales of our products that were impacted by the dynamics of the pandemic were most significant in the early months of the pandemic, with product demand beginning to show some recovery in late 2020. During 2021, there was a gradual recovery in both patient visits and diagnosis rates that approached pre-pandemic levels; however, variants (including Omicron) began to impact the healthcare sector and our business in late 2021 and early 2022. This led to diminished capacity in the healthcare sector and reduced working days for our own sales force. As of the second quarter of 2022, we have seen the impact of these variants recede in most markets, with the exception of some markets in the Asia Pacific region, which has allowed us to engage in increased field-facing activities. Provider and patient activity has also increased, leading to improvements in demand for our products to pre-pandemic levels. However, the cumulative decrease in diagnoses over the course of the pandemic has suppressed the volume of new patients starting treatment, which continues to impact our business. Given the unpredictable nature of the pandemic, there could be intermittent disruptions in physician–patient interactions, and as a result, we may experience quarter-to-quarter variability. In addition, other changes in the healthcare ecosystem have the potential to introduce variability into product sales trends. For example, changes in U.S. employment have led to changes to the insured population. Growth in numbers of Medicaid enrollees and uninsured individuals may have a negative impact on product demand and sales. Overall, uncertainty remains around the timing and magnitude of our sales during the COVID-19 pandemic. See Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2021, and Part II, Item 1A. Risk Factors of our Quarterly Report on Form 10-Q for the period ended March 31,

2022.

Other revenues increased for the three months ended September 30, 2022, due to higher licensing-related revenues. Other revenues increased for the nine months ended September 30, 2022, due to higher revenue from COVID-19 antibody material.

Operating expenses decreased for the three months ended September 30, 2022, primarily due to a licensing-related upfront payment to KKC in 2021. Operating expenses decreased for the nine months ended September 30, 2022, primarily due to the Acquired IPR&D expense related to the Five Prime acquisition and a licensing-related upfront payment to KKC in 2021, partially offset by a loss on a nonstrategic divestiture in 2022. See Note 2, Acquisitions and divestitures.

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,		
	2022	2021	Change	2022	2021	Change
ENBREL	$ 1,106	$ 1,289	(14)%	$ 3,019	$ 3,357	(10)%
Prolia	862	803	7 %	2,636	2,375	11 %
Otezla	627	609	3 %	1,672	1,619	3 %
XGEVA	495	517	(4)%	1,530	1,473	4 %
Aranesp	358	396	(10)%	1,073	1,118	(4)%
Repatha	309	272	14 %	963	844	14 %
KYPROLIS	318	293	9 %	922	824	12 %
Neulasta	247	415	(40)%	905	1,383	(35)%
Nplate	288	273	5 %	838	745	12 %
Other products[1]	1,627	1,453	12 %	4,691	4,288	9 %
Total product sales	$ 6,237	$ 6,320	(1)%	$ 18,249	$ 18,026	1 %

[1] Consists of product sales of our non-principal products, as well as our Gensenta and Bergamo subsidiaries.

Future sales of our products, including the potential impact of the IRA, 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, 2021: (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, 2022 and June 30, 2022: (i) Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of operations—Product sales; and (ii) Part II, Item 1A. Risk Factors.

ENBREL

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

	Three months ended September 30,			Nine months ended September 30,		
	2022	2021	Change	2022	2021	Change
ENBREL — U.S.	$ 1,086	$ 1,263	(14)%	$ 2,965	$ 3,270	(9)%
ENBREL — Canada	20	26	(23)%	54	87	(38)%
Total ENBREL	$ 1,106	$ 1,289	(14)%	$ 3,019	$ 3,357	(10)%

The decrease in ENBREL sales for the three months ended September 30, 2022, was driven by lower net selling price, unfavorable changes to estimated sales deductions and lower unit demand.

The decrease in ENBREL sales for the nine months ended September 30, 2022, was driven by unfavorable changes to estimated sales deductions, lower unit demand and lower net selling price.

For the remainder of 2022, we expect that net selling price will continue to decline driven by increased competition.

Prolia

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

	Three months ended September 30,			Nine months ended September 30,		
	2022	2021	Change	2022	2021	Change
Prolia — U.S.	$ 590	$ 530	11 %	$ 1,783	$ 1,569	14 %
Prolia — ROW	272	273	— %	853	806	6 %
Total Prolia	$ 862	$ 803	7 %	$ 2,636	$ 2,375	11 %

The increase in global Prolia sales for the three and nine months ended September 30, 2022, was driven by higher unit demand.

Otezla

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

	Three months ended September 30,			Nine months ended September 30,		
	2022	2021	Change	2022	2021	Change
Otezla — U.S.	$ 529	$ 495	7 %	$ 1,366	$ 1,284	6 %
Otezla — ROW	98	114	(14)%	306	335	(9)%
Total Otezla	$ 627	$ 609	3 %	$ 1,672	$ 1,619	3 %

The increase in global Otezla sales for the three months ended September 30, 2022, was driven by higher unit demand, partially offset by unfavorable changes to inventory and foreign currency exchange rates.

The increase in global Otezla sales for the nine months ended September 30, 2022, was driven by higher unit demand, partially offset by lower net selling price.

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, 2021, and Part I—Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended June 30, 2022 and September 30, 2022.

XGEVA

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

	Three months ended September 30,			Nine months ended September 30,		
	2022	2021	Change	2022	2021	Change
XGEVA — U.S.	$ 363	$ 372	(2)%	$ 1,122	$ 1,061	6 %
XGEVA — ROW	132	145	(9)%	408	412	(1)%
Total XGEVA	$ 495	$ 517	(4)%	$ 1,530	$ 1,473	4 %

The decrease in global XGEVA sales for the three months ended September 30, 2022, was driven by lower unit demand and unfavorable changes to inventory and foreign currency exchange rates, partially offset by higher net selling price.

The increase in global XGEVA sales for the nine months ended September 30, 2022, was primarily driven by higher net selling price.

Aranesp

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

	Three months ended September 30,			Nine months ended September 30,		
	2022	2021	Change	2022	2021	Change
Aranesp — U.S.	$ 128	$ 149	(14)%	$ 397	$ 409	(3)%
Aranesp — ROW	230	247	(7)%	676	709	(5)%
Total Aranesp	$ 358	$ 396	(10)%	$ 1,073	$ 1,118	(4)%

The decrease in global Aranesp sales for the three months ended September 30, 2022, was primarily driven by lower net selling price and unfavorable changes to foreign currency exchange rates.

The decrease in global Aranesp sales for the nine months ended September 30, 2022, was primarily driven by lower net selling price and unfavorable changes to foreign currency exchange rates, partially offset by favorable changes to estimated sales deductions.

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

Repatha

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

	Three months ended September 30,			Nine months ended September 30,		
	2022	2021	Change	2022	2021	Change
Repatha — U.S.	$ 142	$ 139	2 %	$ 461	$ 421	10 %
Repatha — ROW	167	133	26 %	502	423	19 %
Total Repatha	$ 309	$ 272	14 %	$ 963	$ 844	14 %

The increase in global Repatha sales for the three and nine months ended September 30, 2022, was driven by higher unit demand, partially offset by lower net selling price and unfavorable changes to foreign currency exchange rates. Higher unit demand benefited from contracting changes to support and expand Medicare Part D and commercial patient access and the inclusion of Repatha on China's National Reimbursement Drug List as of January 1, 2022, both of which resulted in decreases to the net selling price in 2022.

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, 2021, and Part I—Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2022, June 30, 2022 and September 30, 2022.

KYPROLIS

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

	Three months ended September 30,			Nine months ended September 30,		
	2022	2021	Change	2022	2021	Change
KYPROLIS — U.S.	$ 217	$ 198	10 %	$ 626	$ 547	14 %
KYPROLIS — ROW	101	95	6 %	296	277	7 %
Total KYPROLIS	$ 318	$ 293	9 %	$ 922	$ 824	12 %

The increase in global KYPROLIS sales for the three and nine months ended September 30, 2022, was driven by higher unit demand, partially offset by unfavorable changes to foreign currency exchange rates.

The FDA has reported that it has granted tentative or final approval of ANDAs for generic carfilzomib products filed by a number of companies. The date of approval of those ANDAs for generic carfilzomib products is governed by the Hatch–Waxman Act and any applicable settlement agreements between us and certain companies that seek to develop generic carfilzomib products.

Neulasta

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

	Three months ended September 30,			Nine months ended September 30,		
	2022	2021	Change	2022	2021	Change
Neulasta — U.S.	$ 205	$ 360	(43)%	$ 772	$ 1,215	(36)%
Neulasta — ROW	42	55	(24)%	133	168	(21)%
Total Neulasta	$ 247	$ 415	(40)%	$ 905	$ 1,383	(35)%

The decrease in global Neulasta sales for the three and nine months ended September 30, 2022, was primarily driven by lower net selling price and unit demand.

Increased competition as a result of biosimilar versions of Neulasta has had and will continue to have a significant adverse impact on brand sales, including accelerating net price erosion and lower unit demand. We also expect other biosimilar versions, including biosimilars that will use an on-body injector that would compete with our Onpro injector, to be approved in the future.

For a discussion of ongoing patent litigations related to these and other biosimilars, 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, 2021, and Part I—Note 13, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2022.

Nplate

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

	Three months ended September 30,			Nine months ended September 30,		
	2022	2021	Change	2022	2021	Change
Nplate — U.S.	$ 162	$ 156	4 %	$ 474	$ 404	17 %
Nplate — ROW	126	117	8 %	364	341	7 %
Total Nplate	$ 288	$ 273	5 %	$ 838	$ 745	12 %

The increase in global Nplate sales for the three months ended September 30, 2022, was driven by higher unit demand and net selling price, partially offset by unfavorable changes to estimated sales deductions and foreign currency exchange rates.

The increase in global Nplate sales for the nine months ended September 30, 2022, was driven by higher unit demand, higher net selling price and favorable changes to estimated sales deductions, partially offset by unfavorable changes to foreign currency exchange rates.

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,		
	2022	2021	Change	2022	2021	Change
MVASI — U.S.	$ 139	$ 187	(26)%	$ 468	$ 617	(24)%
MVASI — ROW	70	87	(20)%	228	245	(7)%
Vectibix — U.S.	106	84	26 %	287	255	13 %
Vectibix— ROW	141	116	22 %	368	375	(2)%
EVENITY — U.S.	136	94	45 %	376	230	63 %
EVENITY— ROW	65	55	18 %	186	157	18 %
BLINCYTO — U.S.	84	74	14 %	240	201	19 %
BLINCYTO — ROW	58	51	14 %	179	139	29 %
EPOGEN — U.S.	136	138	(1)%	392	393	— %
AMGEVITA — ROW	117	111	5 %	341	324	5 %
Aimovig — U.S.	103	77	34 %	289	225	28 %
Aimovig — ROW	4	2	100 %	11	2	*
Parsabiv — U.S.	61	24	*	189	107	77 %
Parsabiv — ROW	39	37	5 %	100	104	(4)%
KANJINTI — U.S.	58	92	(37)%	207	354	(42)%
KANJINTI — ROW	14	24	(42)%	46	79	(42)%
LUMAKRAS — U.S.	61	33	85 %	160	42	*
LUMYKRAS — ROW	14	3	*	54	3	*
NEUPOGEN — U.S.	21	32	(34)%	65	86	(24)%
NEUPOGEN — ROW	14	20	(30)%	45	51	(12)%
TEZSPIRE — U.S.	55	—	NM	91	—	NM
Sensipar — U.S.	4	—	NM	13	4	*
Sensipar/Mimpara — ROW	13	19	(32)%	44	62	(29)%
Other — U.S.[(1)]	80	61	31 %	206	141	46 %
Other — ROW[(1)]	34	32	6 %	106	92	15 %
Total other products	$ 1,627	$ 1,453	12 %	$ 4,691	$ 4,288	9 %
Total U.S. — other products	$ 1,044	$ 896	17 %	$ 2,983	$ 2,655	12 %
Total ROW — other products	583	557	5 %	1,708	1,633	5 %
Total other products	$ 1,627	$ 1,453	12 %	$ 4,691	$ 4,288	9 %

NM = not meaningful

* Change in excess of 100%

(1) Consists of Corlanor, AVSOLA, IMLYGIC and RIABNI, as well as sales by our Gensenta and Bergamo subsidiaries.

Operating expenses

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

	Three months ended September 30,			Nine months ended September 30,		
	2022	2021	Change	2022	2021	Change
Operating expenses:						
Cost of sales	$ 1,588	$ 1,609	(1)%	$ 4,659	$ 4,736	(2)%
% of product sales	25.5 %	25.5 %		25.5 %	26.3 %	
% of total revenues	23.9 %	24.0 %		23.9 %	24.8 %	
Research and development	$ 1,112	$ 1,422	(22)%	$ 3,110	$ 3,471	(10)%
% of product sales	17.8 %	22.5 %		17.0 %	19.3 %	
% of total revenues	16.7 %	21.2 %		16.0 %	18.1 %	
Acquired in-process research and development	$ —	$ —	NM	$ —	$ 1,505	NM
% of product sales	— %	— %		— %	8.3 %	
% of total revenues	— %	— %		— %	7.9 %	
Selling, general and administrative	$ 1,287	$ 1,305	(1)%	$ 3,842	$ 3,943	(3)%
% of product sales	20.6 %	20.6 %		21.1 %	21.9 %	
% of total revenues	19.3 %	19.5 %		19.7 %	20.6 %	
Other	$ 5	$ (8)	*	$ 537	$ 143	*
Total operating expenses	$ 3,992	$ 4,328	(8)%	$ 12,148	$ 13,798	(12)%

NM = not meaningful

* Change in excess of 100%

Cost of sales

Cost of sales was essentially flat, at 23.9% of total revenues for the three months ended September 30, 2022, driven by lower costs associated with COVID-19 antibody shipments and lower manufacturing costs, offset by changes in product mix.

Cost of sales decreased to 23.9% of total revenues for the nine months ended September 30, 2022, driven by lower costs associated with COVID-19 antibody shipments, manufacturing costs and amortization expense from acquisition-related assets, partially offset by changes in product mix.

Research and development

The decrease in R&D expense for the three and nine months ended September 30, 2022, was driven by a licensing-related upfront payment to KKC in 2021 and lower marketed product support, partially offset by higher spend in late-stage development and research and early pipeline programs.

Acquired in-process research and development

The decrease in Acquired IPR&D expense for the nine months ended September 30, 2022, was due to the bemarituzumab program, which was acquired as part of the Five Prime acquisition in 2021. See Note 2, Acquisitions and divestitures.

Selling, general and administrative

The decrease in SG&A expense for the three and nine months ended September 30, 2022, was primarily driven by lower marketed product support.

Other

Other operating expenses for the three months ended September 30, 2022, consisted primarily of an impairment-related 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 a loss on a nonstrategic divestiture. See Note 2, Acquisitions and divestitures.

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

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,	
	2022	2021	2022	2021
Interest expense, net	$ (368)	$ (296)	$ (991)	$ (862)
Other income (expense), net	$ 100	$ 73	$ (747)	$ 97
Provision for income taxes	$ 249	$ 271	$ 662	$ 576
Effective tax rate	10.4 %	12.6 %	11.8 %	12.6 %

Interest expense, net

The increase in Interest expense, net, for the three and nine months ended September 30, 2022, was primarily due to higher overall debt outstanding and higher LIBORs on debt for which we effectively pay a variable rate of interest through the use of interest rate swaps.

Other income (expense), net

The increase in Other income (expense), net, for the three months ended September 30, 2022, was primarily due to the gain recognized on the extinguishment of debt and higher interest income, partially offset by lower current year net gains on our strategic equity investments and higher current year losses in connection with our BeiGene investment.

The decrease in Other income (expense), net, for the nine months ended September 30, 2022, was primarily due to net losses on our strategic equity investments in the current year compared with net gains recognized in the prior year and higher current year net losses in connection with our BeiGene investment, partially offset by the gain recognized on the extinguishment of debt and higher interest income in the current year.

Income taxes

The decrease in our effective tax rate for the three months ended September 30, 2022, was primarily due to the prior year nondeductible IPR&D expense arising from the acquisition of Five Prime and net favorable items, partially offset by a nondeductible loss from a nonstrategic divestiture. The decrease in our effective tax rate for the nine months ended September 30, 2022, was primarily due to the prior year nondeductible IPR&D expense arising from the acquisition of Five Prime, partially offset by current year net unfavorable items compared to last year and a nondeductible loss from a nonstrategic divestiture. See Note 2, Acquisitions and divestitures.

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. If enacted, either by all OECD participants or unilaterally by individual countries, this agreement could result in tax increases in both the United States and foreign jurisdictions. The U.S. Treasury recently released final foreign tax credit regulations that eliminate U.S. creditability of the Puerto Rico Excise Tax beginning in 2023, which would increase our U.S. tax liability. However, the U.S. territory of Puerto Rico recently enacted Act 52-2022, which provides for an alternate fixed tax rate on industrial development income that the U.S. Treasury recently confirmed will be creditable under U.S. law. As part of this new law, eligible businesses would 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 fixed tax rate, we must amend our current tax grant with the Puerto Rico government by December 31, 2022. Once we qualify for this alternative fixed tax rate, which we expect to occur as of January 1, 2023, our tax expense will increase.

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, and we filed a motion to consolidate the two periods into one case in the U.S. Tax Court.

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 have examinations by a number of state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our condensed consolidated financial statements.

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

See Part II, Item 1A, Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability* in our Quarterly Report on Form 10-Q for the period ended June 30, 2022, and Note 4, Income taxes, to the condensed consolidated financial statements for further discussion.

Financial condition, liquidity and capital resources

Selected financial data were as follows (in millions):

	September 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 11,478	$ 8,037
Total assets	$ 63,700	$ 61,165
Current portion of long-term debt	$ 1,543	$ 87
Long-term debt	$ 37,161	$ 33,222
Stockholders' equity	$ 3,653	$ 6,700

Cash, cash equivalents and marketable securities

Our balance of cash, cash equivalents and marketable securities was $11.5 billion as of September 30, 2022. 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, strategic transactions (including those that expand our portfolio of products in areas of therapeutic interest), payment of dividends, stock repurchases and repayment of debt.

We intend to continue to invest in our business while returning capital to stockholders through the payment of cash dividends and stock repurchases, thereby reflecting our confidence in the future cash flows of our business and our desire to optimize our cost of capital. The timing and amount of future dividends and stock repurchases will vary based on a number of factors, including future capital requirements for strategic transactions, availability of financing on acceptable terms, debt service requirements, our credit rating, changes to applicable tax laws or corporate laws, changes to our business model and periodic determination by our Board of Directors that cash dividends and/or stock repurchases are in the best interests of stockholders and are in compliance with applicable laws and the Company's agreements. In addition, the timing and amount of stock repurchases may also be affected by our overall level of cash, stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include block purchases, tender offers, ASRs and market transactions.

In August 2022, March 2022 and December 2021, the Board of Directors declared quarterly cash dividends of $1.94 per share of common stock, which were paid in September 2022, June 2022 and March 2022, respectively, an increase of 10% over the quarterly cash dividend paid each quarter in 2021. In October 2022, the Board of Directors declared a quarterly cash dividend of $1.94 per share of common stock, which will be paid in December 2022.

We also returned capital to stockholders through our stock repurchase program. During the nine months ended September 30, 2022, we executed trades to repurchase $6.3 billion of common stock, including $6.0 billion related to our ASR agreements described below. As of September 30, 2022, $4.6 billion of authorization remained available under our stock repurchase program. In October 2022, the Board of Directors increased the amount authorized under our stock repurchase program by an additional $2.4 billion.

In February 2022, we entered into ASR agreements under which we paid an aggregate amount of $6.0 billion to the Dealers and retired an initial 23.3 million shares of common stock. Approximately $0.9 billion in value of stock remained to be delivered by the Dealers upon final settlement. Final settlement under the ASR agreements occurred in September 2022 resulting in an additional 1.5 million shares received from the Dealers. In total, 24.8 million shares of common stock were repurchased under the ASR agreements.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of September 30, 2022 and December 31, 2021. 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 Annual Report on Form 10-K for the year ended December 31, 2021, Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business*.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant that requires us to maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (consolidated 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, 2022.

Cash flows

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

	Nine months ended September 30,	
	2022	2021
Net cash provided by operating activities	$ 7,072	$ 6,453
Net cash (used in) provided by investing activities	$ (2,571)	$ 963
Net cash used in financing activities	$ (2,988)	$ (1,713)

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, 2022, increased primarily due to higher net income, after adjustments for noncash items, and the impact of working capital items.

Investing

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. Cash provided by investing activities during the nine months ended September 30, 2021, was primarily due to net cash inflows related to marketable securities activity of $3.4 billion, partially offset by the acquisition of Five Prime for $1.6 billion, net of cash acquired, and capital expenditures of $593 million. We currently estimate 2022 spending on capital projects to be approximately $950 million.

Financing

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 discussed above, 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. Cash used in financing activities during the nine months ended September 30, 2021, was primarily due to payments to repurchase our common stock of $3.5 billion and the payment of dividends of $3.0 billion, partially offset by proceeds from the issuance of debt of $4.9 billion. See Note 9, Financing arrangements, and Note 10, 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, 2021.

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, 2021, and is incorporated herein by reference. There were no material changes during the nine months ended September 30, 2022, 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, 2021.

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, 2022.

Management determined that as of September 30, 2022, 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 13, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2022, June 30, 2022 and September 30, 2022, 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, 2021.

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, 2021, 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. These 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 whom payers will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payer dynamics, have limited, and are likely to continue to limit, our ability to set or adjust the price of our products based on their value, which can have a material adverse effect on our business. In the United States, particularly over the past few years, a number of legislative and regulatory proposals have been introduced and/or signed into law that attempt to lower drug prices. These include legislation promulgated by the Inflation Reduction Act of 2022 (IRA) that enables the U.S. government to impose penalties if drug prices are increased at a rate faster than inflation, redesigns Medicare Part D benefits to shift a greater portion of the costs to manufacturers and allows for the U.S. government to set prices for certain drugs in Medicare. Other proposals include limiting drug reimbursement in Medicare and/or the commercial market based on reference prices, or permitting importation of drugs from Canada. Certain proposals focused on drug pricing (such as the IRA) have been adopted, and additional proposals are likely to be adopted and implemented in some form.

—Changing U.S. federal coverage and reimbursement policies and practices have affected and may 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, 2021. Our business has been and will continue to be affected by legislative actions changing U.S. federal reimbursement policy. Congress has focused on drug pricing reforms and oversight since 2018, and this activity is still ongoing and has intensified. For example, in August 2022, the IRA was enacted and includes provisions requiring that: (1) 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 10 drugs in 2026, adding 15 in 2027 and 2028, and adding 20 in 2029 and subsequent years such that approximately one hundred drugs could be subject to such set prices by 2031); (2) Medicare Part D be redesigned to cap beneficiary out-of-pocket costs starting in 2024 and, beginning January 1, 2025, reduce Federal reinsurance in the catastrophic phase (resulting in a shift and increase of such costs to Part D plans and manufacturers, including by requiring discounts from manufacturers on certain drugs); and (3) beginning October 1, 2022, manufacturers will owe rebates on drugs reimbursed under Medicare Part D if price increases outpace inflation, and beginning in January 1, 2023, will owe rebates on drugs reimbursed

under Medicare Part B if price increases outpace inflation. The IRA's drug pricing controls and Medicare redesign is likely to have a material adverse effect on our sales (particularly for our products that are more substantially reliant on Medicare reimbursement), our business and our results of operations. However, as the degree of impact from this legislation on our business depends on a number of implementation decisions, the extent of the IRA's impact on our sales and, in turn, our business remains unclear. Further, following the passage of the IRA, the environment remains dynamic, and in October 2022, the Administration issued an Executive Order on Lowering Prescription Drug Costs for Americans that calls for the HHS to issue a report within 90 days on Innovation Center models that would lower drug costs and promote access to innovative drug therapies for Medicare and Medicaid beneficiaries.

There are other outstanding proposals that, if enacted and implemented, in whole or in part, could also affect access to and sales of our products, including, but not limited to, federal and various state proposals to allow importation of prescription medications from Canada or other countries. See — *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*. In July 2021, the Administration issued an Executive Order designed to address anticompetitive behavior across multiple sectors, and for the healthcare sector, called for, among other things, the FDA to work with states and Indian tribes to develop prescription drug importation programs, more scrutiny of anticompetitive activity by the FTC, emphasized the need for actions to allow for greater competition from generics and biosimilars, and included a process and timeline for federal agencies to deliver to the Administration ideas that address drug pricing. Subsequently, in September 2021, the HHS released a report that presented guiding principles for the Administration's drug pricing proposals, including changes to promote competition throughout the prescription drug industry, highlighting potential legislative policies that Congress could pursue (including drug price negotiation in Medicare Parts B and D, making those negotiated prices available to commercial plans and legislation to speed the entry of biosimilar and generic drugs) and examples of potential administrative tools available to the HHS (including testing various models and enhanced focus of the FTC and the USPTO to address impediments to generic drug and biosimilar competition). Also, in response to the July 2021 Executive Order, the FDA sent a letter to the USPTO describing ways to strengthen coordination between the two agencies, offering training to help identify prior art and seeking USPTO's views on practices that extend market exclusivities, whether pharmaceutical patent examiners need additional resources, and the effect of post-grant challenges at the PTAB on drug patents. In its reply to the FDA, on July 6, 2022, the USPTO affirmed its interest in coordinating with the FDA and outlined specific initiatives, including enhancing procedures for obtaining patents and easing the process for challenging issued patents before the PTAB.

Legislation enacted in 2021 also contained drug pricing reforms. For example, the Infrastructure Investment and Jobs Act includes a provision requiring manufacturers to provide refunds, beginning in 2023, to the government for discarded amounts of certain drugs (including certain Amgen products) from single use containers under Medicare Part B, and CMS recently released proposed regulations to implement this requirement. Also, the American Rescue Plan Act of 2021 includes a provision that increases the Medicaid rebate liability, beginning in 2024, by no longer capping Medicaid rebates at 100% of the Average Manufacturer Price for certain medicines that raise prices in excess of inflation. The implementation of a final rule issued by the HHS that revises regulations under the federal antikickback statute to encourage PBMs to use rebates received from biopharmaceutical manufacturers to reduce patient cost-sharing at the point of sale under Medicare Part D has been delayed to January 1, 2032.

Our business has been, and is expected to continue to be, affected by changes in U.S. federal reimbursement policy resulting from federal regulations and federal demonstration projects. Over the past several years, federal agencies, including the CMS, announced a number of recommendations, policies, proposals and demonstration projects addressing drug pricing. The Administration has also developed and sought to advance a range of policy proposals that could affect U.S. federal reimbursement policy for drugs and biologics, including changes to Medicare Parts B and D. For example, in 2020, in response to an Executive Order, HHS released a rule to allow states to potentially enable the importation of certain drugs from Canada. This rule is in litigation, but should such litigation be unsuccessful, it could allow for the importation of Canadian versions of certain of Amgen's products (including Otezla), that could have a material adverse effect on Amgen's business. Also in response to an Executive Order, CMS previously released an interim final rule to implement the MFN pricing approach aimed at setting the reimbursement rate for 50 Medicare Part B drugs (including our products, such as Prolia, XGEVA, KYPROLIS, Neulasta, Nplate, EPOGEN and Aranesp) equal to the lowest adjusted price in 22 OECD nations for these drugs. In December 2021, subsequent to challenges, including procedural defects, CMS withdrew the MFN rule. Notwithstanding the withdrawal of the rule, the MFN rule's approach to drug pricing and other similar approaches remain of interest to policymakers. In connection with its withdrawal of the MFN rule, CMS noted that it will "… explore all options to incorporate value into payments for Medicare Part B drugs, improve beneficiaries' access to evidence-based care, and reduce drug spending for consumers and throughout the health care system." We expect continued significant focus on healthcare and similar drug pricing proposals for the foreseeable future. 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, in contravention of TEZSPIRE's FDA approved labeling, 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.

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. For example, we believe that CMS's Oncology Care Model demonstration (which has, beginning in 2016, provided participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare costs without negatively affecting the efficacy of care) reduced utilization of certain of our oncology products by participating physician practices. While the Oncology Care Model demonstration ended on June 30, 2022, CMS announced a new oncology model (the Enhancing Oncology Model) that will run for five years (from July 2023 through June 2028) that builds on this prior demonstration program. Further, the HHS's September 2021 comprehensive plan to address drug pricing included potential future mandatory models that link payment for prescription drugs and biologics to factors such as: improved patient outcomes, reductions in health disparities, patient affordability and lower overall costs; bundled payment models; total cost of care models; models in which Medicare Part B savings from utilization of biosimilars, generics or other high-value products are shared between prescribing providers and the government; additional Medicare Part D cost-sharing support for biosimilars and generics; and potential expansion of the Part D Senior Savings Model to additional classes of drugs. CMS also recently finalized a national Medicare coverage determination for certain Alzheimer's disease medications that received accelerated FDA approvals that limits coverage to only patients in qualifying clinical trials, thereby suggesting that accelerated regulatory approval does not necessarily result in full Medicare coverage. Further, pressures on healthcare budgets from the pandemic and the economic downturn remain. We are unable to predict which or how many federal policy, legislative, regulatory, executive or administrative changes may ultimately be, or effectively estimate the consequences to our business if, enacted and implemented. However, to the extent that these or other federal government initiatives further decrease or modify the coverage or reimbursement available for our products, require that we pay increased rebates or shift other costs to us, limit or affect our decisions regarding the pricing of or otherwise reduce the use of our U.S. products, or limit our ability to offer co-pay assistance to commercial patients, such actions could have a material adverse effect on our business and results of operations.

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. The prior Administration finalized a rule (the implementation of which has been delayed by the current Administration) mandating price and cost-sharing transparency for almost all health plans and insurers in the individual and group commercial markets. Further, the current Administration finalized transparency provisions required under the Consolidated Appropriations Act of 2021 for health plans and insurer reporting of certain drug pricing information by December 27, 2022, and each June thereafter, resulting in a biennial public report highlighting drug pricing trends and the impact of prescription drug costs on premiums and out-of-pocket costs. It is unclear how group health plans and health insurers may respond.

—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 or 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. For example, a California law requires biopharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. Similar laws exist in Oregon and Washington. Additional proposals directed at Medicaid seek to penalize manufacturers for price increases above a certain threshold or limit spending on biopharmaceutical products. States are also seeking to change the way they pay for drugs for patients covered by state programs. California adopted a 2020–21 budget that incorporates international pricing into Medicaid supplemental rebate negotiations and allows its Medicaid program to seek federal approval to extend supplemental rebates to non-Medicaid populations. New York has established a Medicaid drug spending cap, and Massachusetts implemented a new review and supplemental rebate negotiation process. Six states (Colorado, Maine, New Hampshire, Maryland, 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 three states (Colorado, Maryland and Washington) include authority for the state PDAB to set upper payment limits on certain drugs in state regulated plans. Other states may consider implementing similar policies and procedures as they face budget deficits from the effects of the COVID-19 pandemic.

Additionally, Colorado, Florida, Maine, New Hampshire, New Mexico and Vermont have enacted laws, and several other states have proposed bills, to implement importation of drugs from Canada. The FDA recently 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 in May 2020 (for plan years starting on or after January 1, 2021, which remains standing policy for 2022) that is subject to litigation and has caused commercial payers to more widely adopt co-pay accumulator adjustment programs. Payers 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, particularly in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable. Payers also control costs by imposing restrictions on access to or usage of our products, such as Step Therapy, or requiring that patients receive the payer's prior authorization before covering the product or that patients use a mail-order pharmacy or a limited network of payer fully-owned mail-order or specialty pharmacies. Payers have also chosen to exclude certain indications for which our products are approved or chosen to exclude coverage entirely. For example, some payers require physicians to demonstrate or document that the patients for whom Repatha has been prescribed meet payer utilization management 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. However, affordability of patient out-of-pocket co-pay cost has limited and may continue to limit patient use. For example, in late 2018 and early 2019, 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 in an attempt to address affordability for patients, particularly those on Medicare, and on December 31, 2019, we discontinued the higher list price option for Repatha. Despite these net and list price reductions, some payers have restricted and may continue to restrict patient access, and have changed and may continue to change formulary coverage for Repatha, and they may seek further discounts or rebates or take other actions that could reduce our sales of Repatha. These factors have served to limit and may continue to limit patient affordability and use, and negatively affect 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 2021, the top five integrated health plans and PBMs controlled about 85% of all pharmacy prescriptions. The consolidation among insurers, PBMs and other payers, including through integrated healthcare delivery systems and/or with specialty or mail-order pharmacies and pharmacy retailers, has increased the negotiating leverage such entities have over us and other biopharmaceutical manufacturers, and has resulted in greater price discounts, rebates and service fees realized by those payers. In 2019, 2020 and 2021, CVS, Express Scripts and United Health Group, respectively, each created Rebate Management Organizations that further increase their respective 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, on June 7, 2022, the FTC launched an inquiry into the business practices of PBMs, and the results of such inquiry could have an effect on manufacturer interactions with PBMs, resulting in changes to access to certain medicines. See our Annual Report on Form 10-K for the year ended December 31, 2021, Part I, Item 1A. Risk Factors—*Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively affect our business.*

—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. See Part I, Item 1. Business—Reimbursement of our Annual Report on Form 10-K for the year ended December 31, 2021.

Pressures to decrease drug expenditures may further intensify 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. IRP has been widely used by many countries outside the United States to control costs based on an external benchmark of a product's price in other countries. IRP policies can 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 European Medicines Agency's approval of Repatha for the treatment of patients with established atherosclerotic disease, the reimbursement for Repatha in France prior to 2020 was limited to a narrower patient population (such as those with homozygous familial hypercholesterolemia (HoFH)) following a national health technology assessment, which had limited our efforts in France to expand Repatha access to the broader patient population covered by the approved label. Some 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.

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

During the three months ended September 30, 2022, 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[2]
July 1 - 31	—		—	$ 4,579,263,848
August 1 - 31	—		—	$ 4,579,263,848
September 1 - 30[1]	1,525,403		1,525,403	$ 4,579,263,848
Total	1,525,403		1,525,403	

[1] As part of the stock repurchase program, the Company entered into ASR agreements with three third-party financial institutions (Dealers) in February 2022. Upon execution of the ASR agreements, the Company made payments in an aggregate amount of $6.0 billion to the Dealers and received and retired an initial 23,258,997 shares of common stock. During September 2022, an additional 1,525,403 shares were received from the Dealers which constituted final settlement under the ASR agreements, and no cash was exchanged as a result of the final settlement. In total, 24,784,400 shares of common stock were delivered under the ASR agreements at an average price of approximately $242.09 per share.

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

Item 6. EXHIBITS

Reference is made to the Index to Exhibits included herein.

INDEX TO EXHIBITS

Exhibit No.	Description
2.1	Asset Purchase Agreement, dated August 25, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.2	Amendment No. 1 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on October 17, 2019 and incorporated herein by reference.)
2.3	Amendment No. 2 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.4	Letter Agreement, dated November 21, 2019, by and between Amgen Inc. and the parties named therein re: Treatment of Certain Product Inventory in connection with Amgen's acquisition of Otezla. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.5	Irrevocable Guarantee, dated August 25, 2019, by and between Amgen Inc. and Bristol-Myers Squibb Company. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.6	Agreement and Plan of Merger, dated 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.)
2.7	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.)
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.6	Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.7	Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.8	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.9	Officers' Certificate of Amgen Inc., dated May 30, 2007, including form of the Company's 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)

Exhibit No.	Description
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	Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.24	Terms of the Bonds for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.25	Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.26	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of 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.)
4.28	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
4.29	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.)
4.30	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.)
4.31	Registration Rights Agreement, dated as of August 17, 2020, by and among Amgen Inc., BofA Securities, Inc. and J.P. Morgan Securities LLC, as lead dealer managers, and BNP Paribas Securities Corp., Deutsche Bank Securities Inc., RBC Capital Markets, LLC, Blaylock Van, LLC and Siebert Williams Shank & Co., LLC, as co-dealer managers. (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)
4.32	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.)
4.33	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.)
4.34	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.)
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 2, 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.)
10.5+	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended and Restated on December 2, 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.)
10.6+	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 Restated on December 2, 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.)
10.8+	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended and Restated on October 21, 2020.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 and incorporated herein by reference.)
10.9+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.10+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.11+	Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)

Exhibit No.	Description
10.12+	Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.13+	First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.14+	Second Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 23, 2019). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.15+	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.)
10.16+	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.)
10.17+	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.)
10.18+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.19+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.20+	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.)
10.21+	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.)
10.22+	Agreement between Amgen Inc. and Peter Griffith, dated October 18, 2019. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)
10.23+	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.)
10.24	Second Amended and Restated Credit Agreement, dated December 12, 2019, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent. (Filed as an exhibit to Form 8-K on December 12, 2019 and incorporated herein by reference.)
10.25	Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)
10.26	Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.27	Letter Agreement, dated June 25, 2019, by and between Amgen Inc. and UCB Celltech (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2019 on July 31, 2019 and incorporated herein by reference.)

Exhibit No.	Description
10.28	Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)
10.29	Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.30	Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.31	Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.32	Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.33	Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
10.34	Side Letter Regarding Collaboration Agreement and Stivarga Agreement, dated February 13, 2020, by and between Onyx Pharmaceuticals, Inc. and Bayer HealthCare LLC. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)
10.35	Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.36*	Amendment No. 1 to Sourcing and Supply Agreement, dated July 14, 2022, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (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.)
10.37	Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.38	Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.39	Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.40	Amendment No. 3 to the Exclusive License and Collaboration Agreement, dated January 31, 2022, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential). (Filed as an exhibit to the Company's Current Report on Form 8-K on January 31, 2022 and incorporated herein by reference.)
10.41	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.)

Exhibit No.	Description
10.42	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.)
10.43	Guarantee, dated as of October 31, 2019, made by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.44	Share Purchase Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.45	Amendment No. 1 to Share Purchase Agreement, dated December 6, 2019, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.46	Restated Amendment No. 2 to Share Purchase Agreement, dated September 24, 2020, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2020 on October 29, 2020 and incorporated herein by reference.)
10.47	Collaboration Agreement dated March 30, 2012 by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, a wholly owned subsidiary of AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted 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.)
10.48	Amendment No. 1 to the Collaboration Agreement, dated October 1, 2014, by and among Amgen Inc., AstraZeneca Collaboration Ventures, LLC and AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted 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.)
10.49	Amendment Nos. 2 through 6 to the March 30, 2012 Collaboration Agreement between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, dated May 2 and 27 and October 2, 2016, January 31, 2018, and May 15, 2020, respectively (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2020 on July 29, 2020 and incorporated herein by reference.)
10.50	Amendment No. 7 to the Collaboration Agreement, dated December 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.)
10.51	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.)
10.52	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.)
10.53	Form of ASR Agreement. (Filed as an exhibit to Form 8-K on February 24, 2022 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.

Exhibit No.	Description
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

(* = filed herewith)

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

(+ = management contract or compensatory plan or arrangement)

SIGNATURES

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

Amgen Inc.
(Registrant)

Date: November 3, 2022

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.

November 3, 2022

/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.

November 3, 2022

/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, 2022 (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.

November 3, 2022

/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, 2022 (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.

November 3, 2022

/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.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDMENT NO. 1 TO AGREEMENT NO. 00135085 BETWEEN AMGEN USA INC. AND DAVITA INC.

This Amendment No. 1 ("Amendment No. 1") to that certain Sourcing and Supply Agreement No. 00135085 (the "Agreement") is made and entered into by and between Amgen USA Inc. ("**Amgen**") and DaVita Inc. ("**Dialysis Center**"). This Amendment No. 1 shall be effective on January 1, 2023 (the "Amendment No. 1 Date").

WHEREAS Amgen and Dialysis Center entered into the Agreement with an effective date of January 6, 2017;

WHEREAS the Agreement contains certain terms, conditions and discount options for the purchase of Amgen ESAs;

WHEREAS Amgen and Dialysis Center desire that the existing Agreement govern in all respects the terms, conditions and discount options for the purchase of Amgen ESAs prior to January 1, 2023, and that the Agreement as amended hereby govern in all respects the terms, conditions and discount options for the purchase of Amgen ESAs from January 1, 2023 to the Term End Date (as such term is amended hereby); and

WHEREAS Amgen and Dialysis Center mutually desire to amend the Agreement as stated below;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants, representations and warranties set forth herein, the Parties agree as follows:

SECTION 1. Definitions; References. Unless otherwise specifically defined herein, each term used herein which is defined in the Agreement shall have the meaning assigned to such term in the Agreement.

SECTION 2. Effectiveness. Each of the amendments and other modifications set forth herein shall be effective on the Amendment No. 1 Date. The amendments and other modifications set forth herein shall have no effect on the terms, conditions and discount options for the purchase of Amgen ESAs prior to January 1, 2023. The rights and obligations of the Parties related to the purchase of Amgen ESAs prior to January 1, 2023 shall continue to be governed by the Agreement as it existed prior to this Amendment No. 1.

SECTION 3. Amendment of Section 2 (Definitions). Section 2 of the Agreement entitled "Definitions" shall be amended such that:

1. The titles and definitions for each of the following Sections are deleted and replaced with the word "*Reserved.*":

   (i) Section 2.2 "Added Aranesp Dialysis Center Purchaser,"

   (ii) Section 2.10 "Alternative Amgen ESA,"

   (iii) Section 2.11 "Alternative Amgen ESA Cover,"

   (iv) Section 2.12 "Alternative ESA Purchase Amount,"

   (v) Section 2.13 "Alternative ESA Purchase Event,"

   (vi) Section 2.16 "Amgen ESA Equivalent Quantity Shortfall,"

   (vii) Section 2.18 "Amgen ESAs Share of Sales,"

(viii) Section 2.33 “Baseline Dose Equivalency Ratio,”

(ix) Section 2.34 “Best Net Aranesp Price Rebate,”

(x) Section 2.35 “Best Net EPOGEN Price Rebate,”

(xi) Section 2.39 “Committed Unit Purchases of Amgen ESAs,”

(xii) Section 2.40 “Committed Unit Purchases of Alternative ESAs,”

(xiii) Section 2.41 “Compensation Data,”

(xiv) Section 2.48 “Dialysis Center Committed Purchasers,”

(xv) Section 2.49 “Dialysis Center Committed Purchasers List,”

(xvi) Section 2.57 “Economic Interest,”

(xvii) Section 2.64 “Forecast Shortfall,”

(xviii) Section 2.65 “Forecast Shortfall Amount,”

(xix) Section 2.69 “HIFs,”

(xx) Section 2.72 “Included HIFs,”

(xxi) Section 2.76 “Initial Dose Equivalency Ratio,”

(xxii) Section 2.79 “Liquidated Damages,”

(xxiii) Section 2.83 “Maximum Aranesp Purchase Limit,”

(xxiv) Section 2.94 “Purchase Commitment Percentage,”

(xxv) Section 2.103 “Self-Reported Data,”

(xxvi) Section 2.104 “Shortfall Amgen ESA,”

(xxvii) Section 2.105 “Significant Supply Shortfall,”

(xxviii) Section 2.115 “Unmet HIF Conversion Volume,”

(xxix) Section 2.117 “Wind-Down Period,” and

(xxx) Section 2.118 “Wind-Down Price.”

2. Section 2.60 of the Agreement entitled “ESAs” is amended and restated as follows:

2.60. “ESAs” shall mean agents that stimulate erythropoiesis including, but not limited to, [*].

3. Section 2.109 of the Agreement entitled “Term End Date” is amended and restated as follows:

2.109 “Term End Date” means December 31, 2023.

4. The following definitions are added to the end of Section 2 immediately following Section 2.118.

2.119 "Amendment No. 1 Date" means January 1, 2023.

2.120 "Annual Purchase Commitment Deficiency" means the difference, if positive, given by (a) the Purchase Commitment for Calendar Year 2023 minus (b) the Qualified Aggregate Purchases of EPOGEN that Dialysis Center Purchasers purchased during Calendar Year 2023.

2.121 "Calendar Year" means a full twelve (12) month period beginning on January 1 and ending December 31 of each year that occurs during the Term.

2.122 "Qualified Aggregate Purchases of EPOGEN" means the amount of EPOGEN purchased by Dialysis Center Purchasers during a given period from an Authorized Wholesaler (or from Amgen pursuant to Section 3.6) for use in providing Dialysis Services, and confirmed by Amgen through sales tracking data, including, without limitation, chargeback data from wholesalers. Qualified Aggregate Purchases of EPOGEN shall be in terms of IUs, net of product returns and adjustments.

SECTION 4. Amendment and Restatement of Section 3 (Purchase and Supply Commitments). Section 3 of the Agreement shall be amended and restated as follows:

3. **PURCHASE AND SUPPLY COMMITMENTS**

3.1. Purchase and Supply Commitments.

3.1.1. Dialysis Center Purchase Commitment. Subject to the terms and conditions of this Agreement, the Dialysis Center Purchasers shall purchase Qualified Aggregate Purchases of EPOGEN during Calendar Year 2023 in an amount not less than the greater of (i) [*] IUs of EPOGEN and (ii) the sum of the quarterly Minimum Forecast Commitments for all Quarters in Calendar Year 2023 (such greater amount, the "Purchase Commitment").

3.1.1.1. Purchase Commitment Deficiency. If during Calendar Year 2023 the Dialysis Center Purchasers do not purchase the quantities of EPOGEN necessary to meet the Purchase Commitment, then Amgen shall deliver to Dialysis Center a notice indicating the Annual Purchase Commitment Deficiency. Within fourteen (14) days of receipt by Dialysis Center of notice from Amgen of the Annual Purchase Commitment Deficiency, Dialysis Center shall make a binding purchase order from one or more Authorized Wholesalers (or from Amgen pursuant to Section 3.6) of EPOGEN in an amount equal to the Annual Purchase Commitment Deficiency and such purchase shall be eligible for the Discounts. Dialysis Center shall promptly provide Amgen notice of the completion of such purchase order along with a copy of the invoice for such purchase order. In the event that Dialysis Center fails to complete such purchase order within fourteen (14) days of receipt of notice from Amgen, Amgen shall offset against any discounts or other amounts owed by Amgen to Dialysis Center an amount equal to the Annual Purchase Commitment Deficiency multiplied by the EPOGEN Fixed Price corresponding to the Qualified Aggregate Purchases of EPOGEN that Dialysis Center Purchasers actually purchased during Calendar Year 2023.

3.1.2. Amgen Supply Commitment. Subject to the terms and conditions of this Agreement, Amgen shall ensure that during each Quarter of the Term [*] percent ([*]%) of the Minimum Forecast Commitment for each such Quarter is available for purchase by the Dialysis Center Purchasers from one or more Authorized Wholesalers or from Amgen pursuant to Section 3.6 (the "Supply Commitment"). Subject to Section 3.2.2, Amgen acknowledges and agrees that nothing in this Agreement shall prohibit any Dialysis Center Purchaser from purchasing an

amount of EPOGEN necessary to satisfy the Purchase Commitment in the final Quarter of the Term regardless of whether such EPOGEN is actually administered by the Dialysis Center Purchasers to their patients for the provision of Dialysis Services during such Quarter.

3.1.3. *Reserved*.

3.1.4. *Reserved*.

3.1.5. Dose Equivalency Ratio. The Parties agree that for purposes of this Agreement the "Dose Equivalency Ratio" between (i) EPOGEN and Mircera is 223:1 such that 223 IUs of EPOGEN shall be considered equivalent to 1 mcg of Mircera, and (ii) the Dose Equivalency Ratio between EPOGEN and any biosimilar of EPOGEN is 1:1.10 such that 1.10 IU of such biosimilar of EPOGEN shall be considered equivalent to 1 IU of EPOGEN.

3.2. Eligible Purchases.

3.2.1. Purchases from Authorized Wholesaler. Only purchases of Amgen ESAs made by a Dialysis Center Purchaser from an Authorized Wholesaler or Amgen pursuant to Section 3.6 shall be eligible to receive the Discounts provided under this Agreement.

3.2.2. Own Use. The Dialysis Center Purchasers shall purchase Amgen ESAs under this Agreement solely for their own use in providing Dialysis Services, and only purchases made by Dialysis Center Purchasers for such use shall be eligible for the Discounts provided under this Agreement. Dialysis Center on behalf of itself and each other Dialysis Center Purchaser covenants that none of them shall seek to procure any of the Discounts available under this Agreement for any purchases of Amgen ESAs not for its or their use in providing Dialysis Services, and Dialysis Center shall promptly notify Amgen in the event Amgen shall have provided any Dialysis Center Purchaser with any Discounts hereunder for any Amgen ESAs that were not used by them for the provision of Dialysis Services.

3.3. Quantity Forecasts and Minimum Forecast Commitment.

3.3.1. Rolling Forecast. Each Quarter during the Term, Dialysis Center shall submit in writing to Amgen a twelve (12) month good faith forecast (or a good faith forecast for such lesser amount of time remaining in the Term) setting forth on a month-by-month basis the aggregate quantities in IUs of EPOGEN anticipated to be purchased by Dialysis Center Purchasers (each, a "Rolling Forecast" and collectively the "Rolling Forecasts"), each such forecast by EPOGEN SKU required for all Dialysis Center Purchasers for each month in the forecast period. The Rolling Forecasts submitted under this Agreement prior to the Amendment No. 1 Date shall continue to be binding as to their EPOGEN forecasts pertaining to Calendar Year 2023, except that if Dialysis Center delivers to Amgen an updated twelve (12) month good faith forecast within thirty (30) days of the date of execution of Amendment No. 1 (which, for the avoidance of doubt, may not update any forecasts for Calendar Year 2022 but may contain equivalent or increased forecasts for the applicable portion of Calendar Year 2023), such updated good faith forecast shall supersede the existing forecast for such portion of Calendar Year 2023 that Dialysis Center submitted to Amgen prior to the execution of Amendment No. 1. Dialysis Center shall submit each Rolling Forecast by no later than the first day of the last month of each Quarter during the Term (e.g., by March 1, 2023 Dialysis Center shall submit a Rolling Forecast for the period from April 2023 through December 2023). If Dialysis Center has not timely delivered a Rolling Forecast as provided above, the Rolling Forecast previously in effect shall remain in effect for the periods covered thereby. The purpose of this Section 3.3.1 is to allow Amgen adequate time to adjust its manufacturing planning and operations to properly reflect the anticipated mix of Available EPOGEN SKUs.

3.3.2. *Reserved.*

3.3.3. Minimum Forecast Commitment. Without reducing or limiting the Purchase Commitment set forth in Section 3.1.1, the forecasted quantities of each Available EPOGEN SKU for months 1-3 of each Rolling Forecast shall constitute the Dialysis Center Purchasers' aggregate minimum purchase commitment of IUs of EPOGEN by Available EPOGEN SKU for such Quarter (the "Minimum Forecast Commitment"). Any forecasted quantity of Available EPOGEN SKUs that constitutes less than one and five-tenths of a percent (1.5%) of the forecasted quantities of total EPOGEN for that Quarter shall be excluded from the Minimum Forecast Commitment and shall not be subject to the Supply Commitment.

3.3.4. *Reserved.*

3.3.5. Forecast Variance. Each new Rolling Forecast submitted by Dialysis Center on a Quarterly basis pursuant to Section 3.3.1 may decrease (but not increase) quantities of each Available EPOGEN SKU for new months 1-6, and may increase or decrease quantities of each Available EPOGEN SKU in the new months 7-12, each from the corresponding months in the immediately prior Rolling Forecast by the "Permitted Percentage Variance" in the table below. The Permitted Percentage Variance for the months of each Rolling Forecast (the "Permitted Variance Period") are as follows:

Old Months	**4-6**	**7-9**	**10-12**	
New Months	**1-3**	**4-6**	**7-9**	**10-12**
EPOGEN: **Percentage Variance Permitted in New Forecast for New Months from Old Months (Same Calendar Months) in Prior Forecast**	[*]% (decrease only)	[*]% (decrease only)	[*]% (decrease or increase)	Initial Rolling Forecast

If Dialysis Center submits a Rolling Forecast that contains a forecast that is not in compliance with the applicable Permitted Percentage Variance, Amgen shall have the right within thirty (30) days of receipt of such Rolling Forecast by written notice to Dialysis Center to either (a) accept such forecast for any month therein that is not in compliance with this Section 3.3.5; or (b) adjust such non-compliant forecasted quantity for any such month to increase or decrease the amount forecasted for such month by up to the minimum amount necessary to bring such forecasted quantity into compliance with this Section 3.3.5. Dialysis Center may, at any time for any good faith reason, request additional variances to the Permitted Percentage Variance and, in such event, the Parties shall work in good faith to accommodate such request; provided, however, that in no event shall Amgen be liable for any resulting Actual Supply Shortfall.

3.3.6. *Reserved.*

3.3.7. Good Faith Estimates. Each Rolling Forecast submitted by Dialysis Center shall represent good faith estimates of the Dialysis Center Purchasers' actual anticipated purchases of EPOGEN for the treatment of dialysis patients in the Territory and reasonable inventory requirements for EPOGEN in the Territory during the relevant timeframes.

3.3.8. Available Amgen ESA SKUs. The Available Amgen ESA SKU Schedule attached as Schedule 3 hereto sets forth the "Available Amgen ESA SKUs" as of the Term Start Date. Amgen may add Available Amgen ESA SKUs to, or remove Available Amgen ESA SKUs (with respect to all purchasers of Amgen ESAs for free-standing dialysis clinics) from, the Available Amgen ESA SKU Schedule upon at least six (6) months advance written notice to Dialysis Center; provided, that Amgen may not remove any Available Amgen ESA SKUs from the Available Amgen ESA SKU Schedule that accounted for five percent (5%) or more of the Qualified Gross Purchases of Amgen ESAs during the immediately preceding three (3) Quarters without the prior written consent of Dialysis Center, which consent may be withheld by Dialysis Center in its sole discretion, unless there is an Available Amgen ESA SKU that corresponds to the same dosage, size and potency of the deleted Available Amgen ESA SKU; and provided further, that, notwithstanding the foregoing, Amgen may immediately remove any Available Amgen ESA SKU should Amgen determine, in its sole discretion, that the removal of any such Available Amgen ESA SKU is for safety or quality or similar reasons. The Parties shall mutually agree upon (a) the first period for which any such new Available Amgen ESA SKU may be ordered by the Dialysis Center Purchasers and (b) any permitted adjustments to the Amgen ESA SKU mix contained in Dialysis Center's then applicable Rolling Forecast to reflect any changes in the Available Amgen ESA SKUs or as otherwise may be required due to any production shortfall applicable to all Amgen ESA customers.

3.4. Supply Commitment Shortfalls.

3.4.1. Amgen Shortfall Activities. Dialysis Center shall promptly notify Amgen and the Amgen Business Representative if the Authorized Wholesalers do not have sufficient quantities of EPOGEN in the aggregate to meet firm purchase orders from the Dialysis Center Purchasers that are within the quantity of EPOGEN that constitutes the Minimum Forecast Commitment for that month, setting forth in such notice the aggregate amount of such EPOGEN that the Authorized Wholesalers are unable to supply. Within seven (7) business days after receipt of such notice from Dialysis Center, Amgen shall use commercially reasonable efforts to (i) deliver to the Authorized Wholesalers additional amounts of EPOGEN, (ii) direct Dialysis Center to one or more Authorized Wholesalers or other wholesalers that have stock of EPOGEN and/or (iii) make other arrangements with Dialysis Center to provide shipment of EPOGEN to Dialysis Center (the "Amgen Shortfall Activities").

3.4.2. An "Actual Supply Shortfall" shall mean, after taking into account EPOGEN identified or made available through Amgen Shortfall Activities, there is not available a quantity of EPOGEN that is part of the Minimum Forecast Commitment for a particular month and constitutes [*] percent ([*]%) or more of the aggregate quantities in IUs of EPOGEN that form the Minimum Forecast Commitment for such month.

3.4.3. Supply Disruption Notice. To the extent permitted by Law and Amgen's internal quality and compliance policies and procedures, Amgen shall provide Dialysis Center with written notice of anticipated supply disruptions for EPOGEN that would impact the Minimum Forecast Commitment.

3.4.3.1. Non-Discrimination and Priority. Subject to any existing obligations that Amgen or any Affiliate of Amgen may have, Amgen shall give Dialysis Center Purchasers' orders first priority among dialysis center purchasers when allocating available EPOGEN during an Actual Supply Shortfall.

3.4.3.2. *Reserved.*

3.4.3.3. Alternative ESA Cover Purchases. If there is limited availability of EPOGEN during an Actual Supply Shortfall, Dialysis Center shall use good faith efforts to procure any Alternative ESAs from a Third Party at the lowest commercially reasonable price. Dialysis Center shall deliver

to Amgen a statement setting forth the aggregate net purchase price (*i.e.*, the aggregate list price less all applicable discounts, rebates, chargebacks and other price adjustments) actually paid by the Dialysis Center Purchasers to any such Third Party for that quantity of Alternative ESAs purchased by such Dialysis Center Purchasers during the Quarter in which the Actual Supply Shortfall occurs solely as a substitute for the Actual Supply Shortfall (the "Aggregate Alternative ESA Net Price"); provided, that, should Dialysis Center be subject to any confidentiality restrictions that Dialysis Center may have with any Third Party from which it procured Alternative ESAs, then the Parties agree to send such Aggregate Alternative ESA Net Price to the Firm to be verified. Amgen shall pay to Dialysis Center an amount of cash equal to the difference, if any, between (a) the Aggregate Alternative ESA Net Price and (b) the product of (i) (1) WAC in effect for the applicable Quarter of the Actual Supply Shortfall less (2) the Discounts per IU of Available EPOGEN SKU earned by the Dialysis Center Purchasers in such Quarter, multiplied by (ii) the amount of the Actual Supply Shortfall.

3.4.4. *Reserved.*

3.4.5. Purchase Commitment Reduction. In the event of an Actual Supply Shortfall, the Purchase Commitment shall be reduced by the amount of the aggregate Actual Supply Shortfall. The foregoing shall be the sole remedy for any Actual Supply Shortfall.

3.4.6. Response to Actual Supply Shortfall. Amgen shall work in good faith to address and end any Actual Supply Shortfall as soon as possible and will use commercially reasonable efforts to make available additional manufacturing capacity.

3.5. WAC. The Dialysis Center Purchasers shall purchase Amgen ESAs from an Authorized Wholesaler (or from Amgen pursuant to Section 3.6) at the then-prevailing WAC (subject to any wholesaler markup, discount, services fees or other charges), and any Discounts shall be applied in accordance with the schedules and terms set forth in Exhibit A and this Agreement. Amgen reserves the right to change WAC at any time, by any amount, without notice. Subsequent to any WAC changes, Amgen shall promptly notify Dialysis Center.

3.6. Authorized Wholesalers. Prior to the Term Start Date, Dialysis Center shall select one or more Authorized Wholesalers from the Authorized Wholesaler list prepared by Amgen and set forth on Exhibit B (as such list may be amended from time to time as provided in this Agreement, the "Authorized Wholesaler List"), and only such selected Authorized Wholesalers shall be Authorized Wholesalers for purposes of this Agreement. From and after the Term Start Date, Dialysis Center shall have the right to change its selection of Authorized Wholesalers from the Authorized Wholesaler List with ninety (90) days prior written notice to Amgen. Dialysis Center may request Amgen to add wholesalers to the Authorized Wholesaler List, and Amgen, at its sole discretion, shall have the right to determine whether to approve of such addition to the Authorized Wholesaler List. Amgen shall have the right to add or remove wholesalers from the Authorized Wholesaler List set forth on Exhibit B in the exercise of its commercially reasonable discretion by ninety (90) days prior written notice to Dialysis Center, provided, that, for any removal, (a) Amgen removes such Authorized Wholesaler with respect to providing Amgen ESAs to all purchasers of Amgen ESAs for free standing dialysis clinics, or (b) such Authorized Wholesaler requests Amgen to remove it as an Authorized Wholesaler for Dialysis Center Purchasers. In the event of any removal of an Authorized Wholesaler from the Authorized Wholesaler List by Amgen, Amgen shall work with Dialysis Center to transition the Dialysis Center Purchasers' purchases of Amgen ESAs to an alternative Authorized Wholesaler, and if no alternative Authorized Wholesaler exists at such time, the Parties shall use reasonable efforts to establish a direct purchasing relationship in any interim period between the removal of the removed Authorized Wholesaler and the initiation of purchases from a new Authorized Wholesaler, if no

Authorized Wholesaler exists at such time. Any such direct purchasing relationship shall be subject to credit qualification and the approval by Amgen of an application for direct ship account. If the Dialysis Center Purchasers purchase Amgen ESAs directly from Amgen as contemplated in this Section 3.6, all purchases of Amgen ESAs made from Amgen by such Dialysis Center Purchasers shall be deemed Qualified Gross Purchases of Amgen ESAs and eligible for the Discounts.

3.7. Dialysis Center Purchasers

3.7.1. Designated Affiliates and Managed Centers. Only the Designated Affiliates listed on Exhibit C (as such list may be amended from time to time as provided in this Agreement, the "Designated Affiliates List") and the Managed Centers set forth on Exhibit D (as such list may be amended from time to time as provided in this Agreement, the "Managed Centers List") shall be Dialysis Center Purchasers for purposes of this Agreement. Dialysis Center shall promptly update and maintain the accuracy of the Designated Affiliates List and the Managed Centers List throughout the Term, but in no event later than thirty (30) days after the addition or removal of a Dialysis Center Purchaser pursuant to Section 3.7.2 or 3.7.3 below. Dialysis Center shall not acquire, divest, restructure, reorganize or reclassify its Affiliates or Managed Centers, or request any addition or removal of any Dialysis Center Purchaser, with the purpose or intent in whole or in part to avoid or eliminate its obligations or commitments, or the obligations and commitments of each of the Dialysis Center Purchasers set forth in this Agreement.

3.7.2. Addition of Dialysis Center Purchasers. After the Term Start Date, subject to the terms and conditions of this Agreement, all new Affiliates that provide Dialysis Services and Managed Centers in the Territory shall be added to this Agreement and become Dialysis Center Purchasers. Dialysis Center shall provide written notice to Amgen of each new Affiliate that provides Dialysis Services and Managed Center in the Territory (each a "Notice of Added Dialysis Center Purchaser"), which notice shall include the proposed Added Dialysis Center Purchaser Transaction Date, plus any additional information regarding the proposed Dialysis Center Purchaser that Amgen shall reasonably request. Subject to the terms and conditions of Section 3.1.1 with respect to the Purchase Commitment, the Designated Affiliates List and the Managed Centers List shall be amended to include such Affiliates that provide Dialysis Services or Managed Centers effective as of (i) thirty (30) days from the date of Amgen's receipt of a Notice of Added Dialysis Center Purchaser or (ii) the applicable Added Dialysis Center Purchaser Transaction Date if such Added Dialysis Center Purchaser Transaction Date is later than thirty (30) days after the Notice of Added Dialysis Center Purchaser (each such effective date, the "Added Dialysis Center Purchaser Effective Date", and each of the Affiliates that provide Dialysis Services and Managed Centers added by such amendments, an "Added Dialysis Center Purchaser"). The Designated Affiliates List and the Managed Centers List shall be amended without further action required of the Parties to reflect additions made in accordance with this Section 3.7.2.

3.7.3. Removal of Dialysis Center Purchasers. (A) Dialysis Center may remove Designated Affiliates from the Designated Affiliates List and Managed Centers from the Managed Center List only (i) upon the written consent of Amgen, which consent shall not be unreasonably withheld, conditioned, and/or delayed or (ii) upon thirty (30) days prior written notice to Amgen in the event such removal is a result of a (a) sale of all or substantially all of the assets or equity interests of a Designated Affiliate to a Third Party, whether by reorganization, merger, sales of assets, or sale of equity interests, (b) permanent closure of a Designated Affiliate facility or (c) termination of the relevant management agreement for a Managed Center that has ceased its management relationship with Dialysis Center and/or any Affiliate of Dialysis Center (each of the events described in this clause (ii), an "Authorized Removal Occurrence"). Dialysis Center shall provide Amgen written notice describing the nature of any requested removal, including the anticipated effective date of any Authorized Removal Occurrence, and such removal shall be

effective thirty (30) days after Amgen has provided Dialysis Center with written consent to such removal or such earlier period as may be agreed to by Amgen or, in the event of an Authorized Removal Occurrence, the effective date of the Authorized Removal Occurrence.

(B) Amgen shall also have the right to remove any Designated Affiliates from the Designated Affiliates List and any Managed Centers from the Managed Centers List upon ninety (90) days (or such shorter period as may be required by Law or any Governmental Authority) written notice to Dialysis Center (a) that such removal is required by order of a court or Governmental Authority or (b) in instances in which Amgen determines, in its reasonable discretion, that such removal is required (i) to comply with Law, based on the advice of counsel, or (ii) as a result of any such Designated Affiliate's or Managed Center's negligence or willful misconduct in the use or administration of Amgen ESAs.

(C) The Designated Affiliates List and the Managed Centers List shall be amended without further action required of the Parties to reflect removals made in accordance with this Section 3.7.3.

3.7.4. Adjustments to Rolling Forecast. Following the addition or removal of an Affiliate that provides Dialysis Services to or from the Designated Affiliates List or a Managed Center to or from the Managed Centers List, the Parties shall mutually agree in good faith to implement any reasonable and necessary adjustments to the Rolling Forecast to account for such addition or removal of an Affiliate that provides Dialysis Services to or from the Designated Affiliates List or a Managed Center to or from the Managed Centers List; provided, that unless otherwise agreed to by the Parties pursuant to Section 3.3.5, Amgen shall have no obligation under Section 3.4 for an Actual Supply Shortfall in the event that any increase to the quantities of each Available EPOGEN SKU set forth in such adjusted Rolling Forecast is in excess of the applicable Permitted Percentage Variances.

3.7.5. *Reserved.*

3.7.6. *Reserved.*

3.7.7. Marketing of Amgen ESAs.

3.7.7.1. Amgen represents and warrants to Dialysis Center that during the Term of this Agreement, neither Amgen, nor any of its agents or representatives, including, without limitation, Amgen's commercial representatives, [*] in the Territory for Amgen ESAs for Dialysis Services [*]. In the event that Dialysis Center has a reasonable basis to believe that Amgen has not complied with its obligations under this Section 3.7.7.1, Dialysis Center shall [*].

3.7.8. Shelf Life. All EPOGEN purchases by Dialysis Center pursuant to this Agreement shall have a minimum of six (6) months remaining dating prior to expiration, unless otherwise agreed to in writing by the Parties.

SECTION 5. Amendment of Section 4.2 (Verification and Audit). The first sentence of Section 4.2 of the Agreement shall be amended and restated as follows:

Discounts (including any qualification criteria for any Discounts) specified herein and/or any other amounts paid by one Party to the other Party pursuant to this Agreement are subject to verification and audit of the relevant purchase and other data (including the Data), as reasonably necessary to calculate any amounts payable hereunder.

SECTION 6. Amendment and Restatement of Section 7 (Other Data). Section 7 of the Agreement shall be amended and restated as follows:

7. *Reserved.*

SECTION 7. Amendment and Restatement of Section 8.4 (HIF Economic Interest). Section 8.4 of the Agreement shall be amended and restated as follows:

8.4 *Reserved.*

SECTION 8. Amendment and Restatement of Section 8.5 (Data). Section 8.5 of the Agreement shall be amended and restated as follows:

8.5 Data. Dialysis Center represents and warrants to Amgen that: (a) the Data that the Dialysis Center Purchasers deliver to Amgen pursuant to Section 6 shall be: (i) prepared and delivered in accordance with the provisions of Section 6 and (ii) as complete and accurate as is reasonably obtainable in view of the Dialysis Center Purchasers' customary method of compilation and the nature and accuracy of the Dialysis Center Purchasers' resources; (b) the Dialysis Center Purchasers shall not knowingly and intentionally misrepresent or omit any of the Data provided by the Dialysis Center Purchasers to Amgen; and (c) Dialysis Center shall promptly notify Amgen in the event it has actual knowledge that any of the Data is not complete and/or accurate.

SECTION 9. Amendment and Restatement of Section 10.2 (Termination for Cause). Section 10.2 of the Agreement shall be amended and restated as follows:

10.2 Termination for Cause. Amgen or Dialysis Center may terminate this Agreement in the event of the following:

10.2.1. Material Breach. Either Party may terminate this Agreement upon thirty (30) days prior written notice if the other Party materially fails to fulfill any of its obligations under this Agreement when they come due and does not cure such breach within thirty (30) days of receipt of such notice.

10.2.2. Termination for Exclusion from Federal Health Care Program. Either Amgen or Dialysis Center may immediately terminate this Agreement upon written notice to the other Party in the event there is change in the other Party's status which excludes it from participation in any "Federal health care program" (as defined under 42 U.S.C. § 1320a-7b(f)) (a "Debarred Party"), provided, that no Party shall have the right to terminate this Agreement pursuant to this Section 10.2.2 if the Debarred Party can complete its obligations through, or otherwise transfer its obligations to, an Affiliate as permitted by applicable Law.

10.2.3. Termination for Payment Failure. Either Party may terminate this Agreement in the event the other Party fails to make payment of any undisputed amount due hereunder in excess of [*] following thirty (30) days' written notice from the Party (which termination shall be automatically effective at the end of such thirty (30) day period should such undisputed amount remain unpaid).

SECTION 10. Amendment and Restatement of Section 10.3 (Liquidated Damages). Section 10.3 of the Agreement shall be amended and restated as follows:

10.3 *Reserved.*

SECTION 11. Amendment and Restatement of Section 10.4 (Effect of Termination). Section 10.4 of the Agreement shall be amended and restated as follows:

10.4 Effect of Termination. Upon any termination or expiration of this Agreement, (a) any earned and vested Discounts shall be paid in accordance with the terms set forth in Exhibit A and (b) any payments by Amgen owing to Dialysis Center under Section 3.4.3.3 shall be paid. All Discounts available to Dialysis Center in the particular Quarter in which such termination occurs shall be paid to Dialysis Center based on an achievement of the eligibility and vesting requirements set forth in Exhibit A.

SECTION 12. Amendment and Restatement of Section 10.5 (Survival). Section 10.5 of the Agreement shall be amended and restated as follows:

10.5 Survival. Any provision that, either expressly or by its nature is intended to survive this Agreement, shall survive any expiration or termination of this Agreement, including Sections 2, 4, 8, 9, 10, and 11.

SECTION 13. Amendment and Restatement of Exhibit A. Exhibit A of the Agreement entitled “Discount Terms and Conditions” shall be deleted in its entirety and replaced with the Exhibit A attached hereto.

SECTION 14. Removal of Exhibit E. Exhibit E of the Agreement entitled “Dialysis Center Committed Purchasers List” shall be deleted in its entirety.

SECTION 15. Removal of Exhibit SR-1. Exhibit SR-1 of the Agreement entitled “Purchase Data Submission Form” shall be deleted in its entirety.

SECTION 16. Amendment and Restatement of Schedule 1. Schedule 1 of the Agreement entitled “Data” shall be deleted in its entirety and replaced with the Schedule 1 attached hereto.

SECTION 17. Removal of Schedule 2. Schedule 2 of the Agreement entitled “Compensation Data” shall be deleted in its entirety.

All other definitions, references, terms, and conditions of the Agreement remain unchanged and in full force and effect.

The Parties have executed this Amendment No. 1 by their designated representatives set forth below.

AMGEN USA INC.

By: /s/ Murdo Gordon

Name (print): Murdo Gordon

Title: EVP Global Commercial Operations

Date: 7/12/2022

DAVITA INC.

By: /s/ Javier Rodriguez

Name (print): Javier Rodriguez

Title: CEO, Kidney Care

Date: 7/14/2022

EXHIBIT A

DISCOUNT TERMS AND CONDITIONS

1. **AMGEN ESA INVOICE DISCOUNTS**

1.1 Base Invoice Discounts. Subject to the terms and conditions contained in the Agreement, Dialysis Center Purchasers shall be entitled to the Base Invoice Discount set forth in the following Base Invoice Discount Table, applied to WAC in effect at the time of purchase of EPOGEN or Aranesp, as applicable, by Dialysis Center Purchasers under the Agreement, exclusive of any wholesaler markup, discount, service fees or other charges:

Base Invoice Discount Table		
PRODUCT	**NDC**	**BASE INVOICE DISCOUNT PERCENTAGE**
EPOGEN	All NDCs	[*]%
Aranesp	All NDCs	[*]%

2. **FIXED PRICE REBATE**

2.1 Definitions. In addition to the defined terms set forth in Section 2 of the Agreement, the following terms, as used in this Exhibit A, shall have the meaning ascribed below.

2.1.1 "Aranesp Fixed Price" shall mean the applicable Aranesp Fixed Price per microgram of Aranesp as set forth in the Aranesp Fixed Price Table below.

Aranesp Fixed Price Table	
Calendar Year	**Aranesp Fixed Price per mcg**
2023	$[*]

2.1.2 "EPOGEN Fixed Price" shall mean the applicable EPOGEN Fixed Price per 1,000 IUs of EPOGEN as set forth below:

EPOGEN Fixed Price Table	
Qualified Aggregate Purchases of EPOGEN in 1,000 IUs by Dialysis Center Purchasers for Calendar Year 2023	**EPOGEN Fixed Price per 1,000 IUs**
≤[*]	$[*]
[*] to [*]	$[*]
[*] to [*]	$[*]
[*]to [*]	$[*]
≥[*]	$[*]

2.1.3 "Aranesp Fixed Price Rebate Percentage" shall mean, at any date of determination, an amount equal to: [(A minus B), divided by A] minus C, where (i) "A" equals Aranesp WAC in effect at time of purchase; (ii) "B" equals Aranesp Fixed Price, and (iii) "C" equals Aranesp Base Invoice Discount Percentage. For example, a determination of the Aranesp Fixed Price Rebate Percentage would be as follows:

Aranesp Fixed Price Rebate Percentage Illustration:

[(Aranesp WAC – Aranesp Fixed Price) / Aranesp WAC] – Aranesp Base Invoice Discount Percentage

2.1.4 "EPOGEN Fixed Price Rebate Percentage" shall mean, at any date of determination, an amount equal to: [(A minus B), divided by A] minus C, where (i) "A" equals EPOGEN WAC in effect at time of purchase; (ii) "B" equals EPOGEN Fixed Price, and (iii) "C" equals EPOGEN Base Invoice Discount Percentage. For example, a determination of the EPOGEN Fixed Price Rebate Percentage would be as follows:

EPOGEN Fixed Price Rebate Percentage Illustration:

[(EPOGEN WAC – EPOGEN Fixed Price) / EPOGEN WAC] – EPOGEN Base Invoice Discount Percentage

2.1.5 "Qualified Gross Purchases of Aranesp" shall mean the amount of Aranesp purchased by Dialysis Center Purchasers during the Term from an Authorized Wholesaler (or from Amgen pursuant to Section 3.6) for use in providing Dialysis Services, and confirmed by Amgen through sales tracking data, including, without limitation, chargeback data from wholesalers. Qualified Gross Purchases of Aranesp shall be calculated using the WAC in effect at the time of the relevant purchase, net of product returns and adjustments.

2.1.6 "Qualified Gross Purchases of EPOGEN" shall mean the amount of EPOGEN purchased by Dialysis Center Purchasers during the Term from an Authorized Wholesaler (or from Amgen pursuant to Section 3.6) for use in providing Dialysis Services, and confirmed by Amgen through sales tracking data, including, without limitation, chargeback data from wholesalers. Qualified Gross Purchases of EPOGEN shall be calculated using the WAC in effect at the time of the relevant purchase, net of product returns and adjustments.

2.2 Aranesp Fixed Price Rebate. Dialysis Center shall earn the Aranesp Fixed Price Rebate for each Calendar Year during the Term in the manner described below in this Section 2.2.

2.2.1 Calculation of Aranesp Fixed Price Rebate. Amgen shall calculate the amount of Dialysis Center's Aranesp Fixed Price Rebate by multiplying the Qualified Gross Purchases of Aranesp during the applicable Calendar Year by the Aranesp Fixed Price Rebate Percentage for such Calendar Year.

2.2.2 Payment of Aranesp Fixed Price Rebate. Amgen will pay such Aranesp Fixed Price Rebate to Dialysis Center (a) in the event of no Annual Purchase Commitment Deficiency, within ninety (90) days after the end of the corresponding Calendar Year, and (b) in the event of an Annual Purchase Commitment Deficiency, within forty-five (45) days after Amgen's receipt of Dialysis Center's notice of completion of Dialysis Center's purchase order of EPOGEN in an amount equal to the Annual Purchase Commitment Deficiency pursuant to Section 3.1.1.1 of the Agreement. The payment of such Aranesp Fixed Price Rebate to Dialysis Center shall be subject to any offset set forth in Section 3.1.1.1 of the Agreement.

2.2.3 Vesting of Aranesp Fixed Price Rebate. The Aranesp Fixed Price Rebate for a given Calendar Year shall vest on the last day of such Calendar Year.

2.3 EPOGEN Fixed Price Rebate. Dialysis Center shall earn the EPOGEN Fixed Price Rebate for each Calendar Year during the Term in the manner described below in this Section 2.3.

2.3.1 Calculation of EPOGEN Fixed Price Rebate. Amgen shall calculate the amount of Dialysis Center's EPOGEN Fixed Price Rebate by multiplying the Qualified Gross Purchases of EPOGEN during the applicable Calendar Year by the EPOGEN Fixed Price Rebate Percentage for such Calendar Year.

2.3.2 Payment of EPOGEN Fixed Price Rebate. Amgen will pay such EPOGEN Fixed Price Rebate to Dialysis Center (a) in the event of no Annual Purchase Commitment Deficiency, within ninety (90) days after the end of the corresponding Calendar Year, and (b) in the event of an Annual Purchase Commitment Deficiency, within forty-five (45) days after Amgen's receipt of Dialysis Center's notice of completion of Dialysis Center's purchase order of EPOGEN in an amount equal to the Annual Purchase Commitment Deficiency pursuant to Section 3.1.1.1 of the Agreement. The payment of such EPOGEN Fixed Price Rebate to Dialysis Center shall be subject to any offset set forth in Section 3.1.1.1 of the Agreement.

2.3.3 Vesting of EPOGEN Fixed Price Rebate. The EPOGEN Fixed Price Rebate for a given Calendar Year shall vest on the last day of such Calendar Year.

2.3.4

Schedule 1

Data

Category	Data Element	Facility	Patient
Facility Reference	Facility Name		
	Address		
	City, State, Zip		
	Phone		
	Facility ID (unique within account)		
	Regional ID (unique within account)		
	State in which facility is located		
Patient Demographics	De-identified Patient ID		
Medications	ESA Name		
	ESA Dose [*]		
	EPOGEN Administration Frequency (On DVA offered Protocol)		
	Aranesp Administration Frequency*		
	Other ESA Administration Frequency*		
	ESA Route of Administration		
	ESA Start Date		
	ESA Stop Date (Missed dose due to held)*		

* For designated fields, Dialysis Center will provide Amgen business rules to calculate value of the field based on the submitted Data.