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 June 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 August 1, 2022, the registrant had 534,930,850 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
2017 Tax Act	Tax Cuts and Jobs Act of 2017
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.
EMA	European Medicines Agency
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
IRP	international reference pricing
IRS	Internal Revenue Service
LIBOR	London Interbank Offered Rate
Lp(a)	lipoprotein(a)
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
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)
Olpasiran	Olpasiran (formerly AMG 890)
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 June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Revenues:				
Product sales	$ 6,281	$ 6,114	$ 12,012	$ 11,706
Other revenues	313	412	820	721
Total revenues	6,594	6,526	12,832	12,427
Operating expenses:				
Cost of sales	1,510	1,637	3,071	3,127
Research and development	1,039	1,082	1,998	2,049
Acquired in-process research and development	—	1,505	—	1,505
Selling, general and administrative	1,327	1,384	2,555	2,638
Other	542	90	532	151
Total operating expenses	4,418	5,698	8,156	9,470
Operating income	2,176	828	4,676	2,957
Other income (expense):				
Interest expense, net	(328)	(281)	(623)	(566)
Other (expense) income, net	(317)	11	(847)	24
Income before income taxes	1,531	558	3,206	2,415
Provision for income taxes	214	94	413	305
Net income	$ 1,317	$ 464	$ 2,793	$ 2,110
Earnings per share:				
Basic	$ 2.46	$ 0.81	$ 5.16	$ 3.67
Diluted	$ 2.45	$ 0.81	$ 5.13	$ 3.65
Shares used in calculation of earnings per share:				
Basic	535	573	541	575
Diluted	537	576	544	578

See accompanying notes.

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

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Net income	$ 1,317	$ 464	$ 2,793	$ 2,110
Other comprehensive income (loss), net of reclassification adjustments and taxes:				
Foreign currency translation	(65)	14	(116)	(25)
Cash flow hedges	156	(48)	240	142
Other	—	(1)	—	—
Other comprehensive income (loss), net of reclassification adjustments and taxes	91	(35)	124	117
Comprehensive income	$ 1,408	$ 429	$ 2,917	$ 2,227

See accompanying notes.

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

	June 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,203	$ 7,989
Marketable securities	1,980	48
Trade receivables, net	5,327	4,895
Inventories	4,554	4,086
Other current assets	2,258	2,367
Total current assets	19,322	19,385
Property, plant and equipment, net	5,158	5,184
Intangible assets, net	13,927	15,182
Goodwill	14,865	14,890
Other noncurrent assets	6,022	6,524
Total assets	$ 59,294	$ 61,165
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,256	$ 1,366
Accrued liabilities	10,545	10,731
Current portion of long-term debt	817	87
Total current liabilities	12,618	12,184
Long-term debt	35,705	33,222
Long-term tax liabilities	5,603	6,594
Other noncurrent liabilities	2,949	2,465
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding—534.9 shares in 2022 and 558.3 shares in 2021	31,343	32,096
Accumulated deficit	(28,252)	(24,600)
Accumulated other comprehensive loss	(672)	(796)
Total stockholders' equity	2,419	6,700
Total liabilities and stockholders' equity	$ 59,294	$ 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

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

See accompanying notes.

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

	Six months ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net income	$ 2,793	$ 2,110
Depreciation, amortization and other	1,669	1,696
Deferred income taxes	(514)	(137)
Acquired in-process research and development	—	1,505
Adjustments for equity method investments	497	(36)
Loss on divestiture	560	—
Other items, net	436	206
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	(504)	35
Inventories	(410)	(167)
Other assets	198	(258)
Accounts payable	(98)	(156)
Accrued income taxes, net	(685)	(930)
Long-term tax liabilities	108	47
Other liabilities	44	120
Net cash provided by operating activities	4,094	4,035
Cash flows from investing activities:		
Purchases of marketable securities	(1,976)	(8,000)
Proceeds from sales of marketable securities	—	4,404
Proceeds from maturities of marketable securities	47	6,528
Purchases of property, plant and equipment	(436)	(351)
Cash paid for acquisitions, net of cash acquired	—	(1,626)
Other	61	(65)
Net cash (used in) provided by investing activities	(2,304)	890
Cash flows from financing activities:		
Net proceeds from issuance of debt	3,954	—
Repurchases of common stock (Note 10)	(6,360)	(2,452)
Dividends paid	(2,118)	(2,024)
Other	(52)	(85)
Net cash used in financing activities	(4,576)	(4,561)
(Decrease) increase in cash and cash equivalents	(2,786)	364
Cash and cash equivalents at beginning of period	7,989	6,266
Cash and cash equivalents at end of period	$ 5,203	$ 6,630

See accompanying notes.

1. Summary of significant accounting policies

Business

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

Basis of presentation

The financial information for the three and six months ended June 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 Report on Form 10-Q for the period ended March 31, 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 $9.0 billion and $8.8 billion as of June 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 condensed 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 six months ended June 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 six months ended June 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 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 (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 leading 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 June 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.

Our accounting for this acquisition is preliminary and will be finalized upon completion of our analysis of certain tax-related items as we obtain additional information during the measurement period of up to one year from the acquisition date.

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 trial-ready, first-in-class program for gastric cancer. Five Prime's operations have been included in our condensed consolidated financial statements commencing after the acquisition date.

We allocated the consideration to acquire Five Prime to: the bemarituzumab 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 will acquire all of our shares in Gensenta—a subsidiary in Turkey. Net assets related to Gensenta of $80 million met the criteria to be classified as held-for-sale and did not meet the criteria to be classified as discontinued operations. Upon closing of the transaction, we expect to receive $135 million in cash. The transaction is expected to close in the third quarter of 2022 upon approval by the Turkish Competition Authority.

As of June 30, 2022, held-for-sale assets and liabilities of $100 million and $20 million were included in Other current assets and Accrued liabilities, respectively, in the Condensed Consolidated Balance Sheets. During the three months ended June 30, 2022, we recognized a loss of $560 million recorded to 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 June 30,					
	2022			2021		
	U.S.	ROW	Total	U.S.	ROW	Total
ENBREL	$ 1,036	$ 15	$ 1,051	$ 1,113	$ 31	$ 1,144
Prolia	611	311	922	538	276	814
Otezla	487	107	594	423	111	534
XGEVA	391	142	533	355	133	488
Aranesp	132	225	357	135	232	367
Neulasta	263	47	310	434	52	486
Repatha	154	171	325	143	143	286
KYPROLIS	213	104	317	190	90	280
Nplate	156	128	284	136	109	245
Other products	1,003	585	1,588	907	563	1,470
Total product sales[(1)]	$ 4,446	$ 1,835	6,281	$ 4,374	$ 1,740	6,114
Other revenues			313			412
Total revenues			$ 6,594			$ 6,526

	Six months ended June 30,					
	2022			2021		
	U.S.	ROW	Total	U.S.	ROW	Total
ENBREL	$ 1,879	$ 34	$ 1,913	$ 2,007	$ 61	$ 2,068
Prolia	1,193	581	1,774	1,039	533	1,572
Otezla	837	208	1,045	789	221	1,010
XGEVA	759	276	1,035	689	267	956
Aranesp	269	446	715	260	462	722
Neulasta	567	91	658	855	113	968
Repatha	319	335	654	282	290	572
KYPROLIS	409	195	604	349	182	531
Nplate	312	238	550	248	224	472
Other products	1,939	1,125	3,064	1,759	1,076	2,835
Total product sales[(1)]	$ 8,483	$ 3,529	12,012	$ 8,277	$ 3,429	11,706
Other revenues			820			721
Total revenues			$ 12,832			$ 12,427

[(1)] Hedging gains and losses, which are included in product sales, were not material for the three and six months ended June 30, 2022 and 2021.

4. Income taxes

The effective tax rates for the three and six months ended June 30, 2022, were 14.0% and 12.9%, respectively, compared with 16.8% and 12.6%, respectively, for the corresponding periods of the prior year.

The decrease in our effective tax rate for the three months ended June 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 unfavorable items including a loss on a nonstrategic divestiture. The increase in our effective tax rate for the six months ended June 30, 2022, was primarily due to current year unfavorable items compared to last year including a loss on a nonstrategic divestiture, partially offset by the prior year nondeductible IPR&D expense arising from the acquisition of Five Prime and changes in earnings mix. The effective tax rates differ from the federal statutory rate primarily as a result of foreign earnings from the Company's operations conducted in Puerto Rico, a territory of the United States treated as a foreign jurisdiction for U.S. tax purposes, that are 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 will seek consolidation of 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 Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations, Income Taxes, for further discussion and Part II, Item 1A, Risk Factors—*The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability*.

During the three and six months ended June 30, 2022, the gross amounts of our UTBs increased by $50 million and $95 million, respectively, as a result of tax positions taken during the current year. Substantially all of the UTBs as of June 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 June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Income (Numerator):				
Net income for basic and diluted EPS	$ 1,317	$ 464	$ 2,793	$ 2,110
Shares (Denominator):				
Weighted-average shares for basic EPS	535	573	541	575
Effect of dilutive securities	2	3	3	3
Weighted-average shares for diluted EPS	537	576	544	578
Basic EPS	$ 2.46	$ 0.81	$ 5.16	$ 3.67
Diluted EPS	$ 2.45	$ 0.81	$ 5.13	$ 3.65

For the three and six months ended June 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 June 30, 2022	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ —	$ —	$ —	$ —
U.S. Treasury bills	1,980	—	—	1,980
Money market mutual funds	4,433	—	—	4,433
Other short-term interest-bearing securities	—	—	—	—
Total interest-bearing securities	$ 6,413	$ —	$ —	$ 6,413

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	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 4,433	$ 7,256
Marketable securities	1,980	48
Total interest-bearing securities	$ 6,413	$ 7,304

Cash and cash equivalents in the above table excludes bank account cash of $770 million and $733 million as of June 30, 2022 and December 31, 2021, respectively.

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

For the three and six months ended June 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 (expense) income, net, in the Condensed Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

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

Equity securities

We held investments in equity securities with readily determinable fair values (publicly traded securities) of $361 million and $611 million as of June 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 June 30, 2022 and 2021, net unrealized gains and losses on publicly traded securities were a $106 million net loss and a $25 million net gain, respectively. During the six months ended June 30, 2022 and 2021, net unrealized losses on publicly traded securities were $276 million and $31 million, respectively. Realized gains and losses on sales of publicly traded securities for the three and six months ended June 30, 2022 and 2021, were not material.

We held investments of $280 million and $262 million in equity securities without readily determinable fair values as of June 30, 2022 and December 31, 2021, respectively, which are included in Other noncurrent assets in the Condensed Consolidated Balance Sheets. During the three and six months ended June 30, 2022 and 2021, upward adjustments and downward adjustments on these securities were not material. Adjustments were based on observable price transactions.

Equity method investments

BeiGene, Ltd.

As of June 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 (expense) income, net, in the Condensed Consolidated Statements of Income one quarter in arrears.

During the three months ended June 30, 2022 and 2021, the carrying value of our equity investment was adjusted by our share of BeiGene's net loss of $80 million and net income of $14 million, respectively, and amortization of the basis difference of $48 million and $42 million, respectively. During the six months ended June 30, 2022 and 2021, the carrying value of our equity investment was adjusted by our share of BeiGene's net losses of $188 million and $83 million, respectively, and amortization of the basis difference of $95 million and $84 million, respectively. As of June 30, 2022 and December 31, 2021, the carrying values of our investment in BeiGene totaled $2.5 billion and $2.8 billion, respectively, and the fair values of our investment totaled $3.1 billion and $5.1 billion, respectively. As of June 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. As of June 30, 2022 and December 31, 2021, our ownership interest in Neumora was approximately 25.7% and 25.9%, respectively, and the fair values of our investment were $131 million and $220 million, respectively. Accordingly, for the reduction in fair value of our investment during the three and six months ended June 30, 2022, we recognized a loss of $39 million and $89 million, respectively, for the reduction in fair value of our investment in Other (expense) income, 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 $338 million and $573 million as of June 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 June 30, 2022, unfunded additional commitments to be made for these investments during the next several years were $209 million. For the three months ended June 30, 2022 and 2021, net unrealized losses from our limited partnership investments were $60 million and $43 million, respectively. For the six months ended June 30, 2022 and 2021, net unrealized gains and losses from our limited partnership investments were a $220 million net loss and a $165 million net gain, respectively.

7. Inventories

Inventories consisted of the following (in millions):

	June 30, 2022	December 31, 2021
Raw materials	$ 779	$ 647
Work in process	2,763	2,367
Finished goods	1,012	1,072
Total inventories	$ 4,554	$ 4,086

8. Goodwill and other intangible assets

Goodwill

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

	Six months ended June 30, 2022
Beginning balance	$ 14,890
Adjustments to goodwill resulting from acquisitions and divestitures, net[(1)]	7
Currency translation adjustment	(32)
Ending balance	$ 14,865

[(1)] Composed 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):

	June 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	$ 25,537	$ (13,863)	$ 11,674	$ 25,561	$ (12,769)	$ 12,792
Licensing rights	3,864	(3,050)	814	3,807	(2,973)	834
Marketing-related rights	1,326	(1,125)	201	1,354	(1,112)	242
Research and development technology rights	1,371	(1,153)	218	1,377	(1,133)	244
Total finite-lived intangible assets	32,098	(19,191)	12,907	32,099	(17,987)	14,112
Indefinite-lived intangible assets:						
In-process research and development	1,020	—	1,020	1,070	—	1,070
Total other intangible assets	$ 33,118	$ (19,191)	$ 13,927	$ 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 June 30, 2022 and 2021, we recognized amortization associated with our finite-lived intangible assets of $629 million and $652 million, respectively. During the six months ended June 30, 2022 and 2021, we recognized amortization associated with our finite-lived intangible assets of $1.3 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 six months ending December 31, 2022, and the years ending December 31, 2023, 2024, 2025, 2026 and 2027, are $1.3 billion, $2.5 billion, $2.5 billion, $2.4 billion, $1.7 billion and $1.8 billion, respectively.

9. Financing arrangements

Our borrowings consisted of the following (in millions):

	June 30, 2022	December 31, 2021
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	$ 733	$ 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)	786	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)	579	643
2.20% notes due 2027 (2.20% 2027 Notes)	1,750	1,750
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
1.65% notes due 2028 (1.65% 2028 Notes)	1,250	1,250
3.00% notes due 2029 (3.00% 2029 Notes)	750	—
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	853	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)	1,250	1,250
3.35% notes due 2032 (3.35% 2032 Notes)	1,000	—
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)	1,150	1,150
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	729	729
5.65% notes due 2042 (5.65% 2042 Notes)	415	415
5.375% notes due 2043 (5.375% 2043 Notes)	185	185
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415
3.375% notes due 2050 (3.375% 2050 Notes)	2,250	2,250
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
3.00% notes due 2052 (3.00% 2052 Notes)	1,350	1,350
4.20% notes due 2052 (4.20% 2052 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	(1,245)	(1,213)
Fair value adjustments	(210)	284
Other	13	15
Total carrying value of debt	36,522	33,309
Less current portion	(817)	(87)
Total long-term debt	$ 35,705	$ 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.

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.

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
Total stock repurchases	24.6	$ 5,410	10.2	$ 2,457

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 remains to be delivered by the Dealers pending final settlement. The final number of shares to be repurchased by the Company will be based on the daily volume-weighted average stock price of the Company's common stock during the terms of the ASR agreements, less a discount and subject to adjustments pursuant to the terms and conditions of the ASR agreements. At settlement, under certain circumstances, one or more of the Dealers may be required to deliver additional shares of common stock to the Company, or under certain circumstances, the Company may be required to deliver shares of common stock or to make a cash payment, at its election, to a Dealer. The final settlement under the ASR agreements is scheduled to occur in the third quarter of 2022, subject to an earlier termination under certain limited circumstances, as set forth in the ASR agreements. In total, we repurchased 24.6 million shares of common stock in the first quarter of 2022, including shares received under the ASR agreements.

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

Dividends

In March 2022 and December 2021, the Board of Directors declared a quarterly cash dividend of $1.94 per share, which were paid in June 2022 and March 2022, respectively. In August 2022, the Board of Directors declared a quarterly cash dividend of $1.94 per share, which will be paid on September 8, 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)

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

	Three months ended June 30,		
Components of AOCI	2022	2021	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract gains (losses)	$ 53	$ (18)	Product sales
Cross-currency swap contract (losses) gains	(185)	46	Other (expense) income, net
	(132)	28	Income before income taxes
	28	(6)	Provision for income taxes
	$ (104)	$ 22	Net income

	Six months ended June 30,		
Components of AOCI	2022	2021	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract gains (losses)	$ 80	$ (19)	Product sales
Cross-currency swap contract losses	(263)	(86)	Other (expense) income, net
	(183)	(105)	Income before income taxes
	39	22	Provision for income taxes
	$ (144)	$ (83)	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 source of inputs as follows:

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

The availability of observable inputs can vary among 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 June 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	1,980	—	—	1,980
Money market mutual funds	4,433	—	—	4,433
Other short-term interest-bearing securities	—	—	—	—
Equity securities	361	—	131	492
Derivatives:				
Foreign currency contracts	—	413	—	413
Cross-currency swap contracts	—	29	—	29
Interest rate swap contracts	—	—	—	—
Total assets	$ 6,774	$ 442	$ 131	$ 7,347
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 30	$ —	$ 30
Cross-currency swap contracts	—	503	—	503
Interest rate swap contracts	—	591	—	591
Contingent consideration obligations	—	—	310	310
Total liabilities	$ —	$ 1,124	$ 310	$ 1,434

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
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. 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 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 June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Beginning balance	$ 330	$ 39	$ 342	$ 33
Payments	(1)	(2)	(3)	(3)
Net changes in valuations	(19)	11	(29)	18
Ending balance	$ 310	$ 48	$ 310	$ 48

As of June 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 June 30, 2022 and December 31, 2021, the aggregate fair values of our borrowings were $34.4 billion and $37.9 billion, respectively, and the carrying values were $36.5 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 June 30, 2022 and December 31, 2021, the fair values were $3.1 billion and $5.1 billion, and the carrying values were $2.5 billion and $2.8 billion, respectively.

During the three and six months ended June 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 are being hedged than in successive periods.

As of June 30, 2022 and December 31, 2021, we had outstanding foreign currency forward contracts with aggregate notional amounts of $5.6 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 (expense) income, net, in the Condensed Consolidated Statements of Income in the same periods during which the hedged debt affects earnings.

The notional amounts and interest rates of our cross-currency swaps as of June 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	4.5 %

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Condensed Consolidated Balance Sheets and are amortized into Interest expense, net, in the Condensed Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the six months ended June 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 June 30,		Six months ended June 30,	
Derivatives in cash flow hedging relationships	**2022**	**2021**	**2022**	**2021**
Foreign currency contracts	$ 252	$ (46)	$ 330	$ 137
Cross-currency swap contracts	(185)	15	(207)	(60)
Total unrealized gains (losses)	$ 67	$ (31)	$ 123	$ 77

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified for and were designated as fair value hedges. These interest rate swap contracts effectively convert fixed-rate coupons to floating-rate LIBOR-based coupons over the terms of the related hedge contracts. As of both June 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	**June 30, 2022**	**December 31, 2021**	**June 30, 2022**	**December 31, 2021**
Current portion of long-term debt	$ 82	$ 85	$ 82	$ 85
Long-term debt	$ 6,241	$ 6,729	$ (292)	$ 199

[1] Current portion of long-term debt includes $82 million and $85 million of carrying value with discontinued hedging relationships as of June 30, 2022 and December 31, 2021, respectively. Long-term debt includes $399 million and $440 million of carrying value with discontinued hedging relationships as of June 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 June 30, 2022 and December 31, 2021, respectively. Long-term debt includes $299 million and $340 million of hedging adjustments on discontinued hedging relationships as of June 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 June 30, 2022			Six months ended June 30, 2022		
	Product sales	Other (expense) income, net	Interest expense, net	Product sales	Other (expense) income, net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Condensed Consolidated Statements of Income	$ 6,281	$ (317)	$ (328)	$ 12,012	$ (847)	$ (623)
The effects of cash flow and fair value hedging:						
Gains (losses) on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency contracts	$ 53	$ —	$ —	$ 80	$ —	$ —
Cross-currency swap contracts	$ —	$ (185)	$ —	$ —	$ (263)	$ —
Gains (losses) on fair value hedging relationships—interest rate swap agreements:						
Hedged items[1]	$ —	$ —	$ 157	$ —	$ —	$ 494
Derivatives designated as hedging instruments	$ —	$ —	$ (135)	$ —	$ —	$ (450)

	Three months ended June 30, 2021			Six months ended June 30, 2021		
	Product sales	Other (expense) income, net	Interest expense, net	Product sales	Other (expense) income, net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Condensed Consolidated Statements of Income	$ 6,114	$ 11	$ (281)	$ 11,706	$ 24	$ (566)
The effects of cash flow and fair value hedging:						
(Losses) gains on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency contracts	$ (18)	$ —	$ —	$ (19)	$ —	$ —
Cross-currency swap contracts	$ —	$ 46	$ —	$ —	$ (86)	$ —
(Losses) gains on fair value hedging relationships—interest rate swap agreements:						
Hedged items[1]	$ —	$ —	$ (34)	$ —	$ —	$ 141
Derivatives designated as hedging instruments	$ —	$ —	$ 55	$ —	$ —	$ (97)

[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 June 30, 2022, we expected to reclassify $179 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 June 30, 2022 and December 31, 2021, the total notional amounts of these foreign currency forward contracts were $550 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 six months ended June 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	
June 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	$ 413	Accrued liabilities/ Other noncurrent liabilities	$ 30
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	29	Accrued liabilities/ Other noncurrent liabilities	503
Interest rate swap contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	591
Total derivatives designated as hedging instruments		$ 442		$ 1,124

	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 June 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 Report on Form 10-Q for the period ended March 31, 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 Report on Form 10-Q for the period ended March 31, 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 Report on Form 10-Q for the period ended March 31, 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 June 14, 2022, Amgen filed a lawsuit in the U.S. District Court for the District of New Jersey (the New Jersey District Court) against Apotex Inc. (Apotex) 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. This lawsuit was 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

Patent Disputes in the International Region

On July 21, 2022, Sanofi Biotechnology SAS filed an action against Amgen GmbH and Amgen (Europe) B.V. before the Regional Court of Dusseldorf alleging that the marketing and sale of Repatha infringes European Patent No. 2,756,004 (the EP'004 Patent), seeking infringement damages and injunctive relief. The EP'004 Patent is currently in opposition proceedings, initiated by Amgen and an anonymous third party, before the European Patent Office (EPO). A hearing before the Opposition Division of the EPO was held on June 8 and 9, 2022, and the Opposition Division upheld the validity of the claims at issue with narrowing amendments. The parties are awaiting the Opposition Division's written opinion. Amgen filed a Notice of Appeal on July 6, 2022.

Antitrust Actions

Sensipar Antitrust Class Actions

On May 11, 2022, the parties filed motions asking permission to seek interlocutory appeal of the U.S. District Court for the District of Delaware's (the Delaware District Court's) March 11, 2022 order denying Amgen's Motion to Dismiss solely with respect to the reverse payment claim and the various state law claims. The plaintiffs did not oppose Amgen's motion and instead argued all issues should be appealed at this time. Amgen filed its opposition to plaintiffs' motion on June 10, 2022, and reply briefs were filed on June 24, 2022.

HUMIRA® Biosimilar Antitrust Actions

On August 1, 2022, the U.S. Court of Appeals for the Seventh Circuit issued an opinion affirming the June 30, 2020 dismissal with prejudice by the U.S. District Court for the Northern District of Illinois of a consolidated complaint against Amgen along with AbbVie Inc., AbbVie Biotechnology Ltd., Samsung Bioepis Co. and Sandoz Inc.

Regeneron Pharmaceuticals, Inc. Antitrust Action

On May 27, 2022, Regeneron Pharmaceuticals, Inc. (Regeneron) filed suit against Amgen in the Delaware District Court for federal and state antitrust and unfair competition violations and tortious interference with prospective business relations. Regeneron alleges that Amgen's sales contracting practices for Repatha, ENBREL and Otezla with key insurers, third-party payors and PBMs have harmed the sales of its product PRALUENT® and focuses on two primary arguments: that Amgen improperly bundled sales of Repatha with ENBREL, Otezla and potentially other products and sought exclusive or de facto exclusive formulary positioning for Repatha. Amgen's initial responsive pleading was filed on August 1, 2022.

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.

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 Report on Form 10-Q for the period ended March 31, 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 Report on Form 10-Q for the period ended March 31, 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, Neulasta, Repatha, KYPROLIS and Nplate. We also market a number of other products, including MVASI, Vectibix, EVENITY, BLINCYTO, EPOGEN, AMGEVITA, Aimovig, Parsabiv, KANJINTI, LUMAKRAS/LUMYKRAS, NEUPOGEN, Sensipar/Mimpara and TEZSPIRE.

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 Risk Factors 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 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 March 31, 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 Report on Form 10-Q for the period ended March 31, 2022.

Products/Pipeline

General Medicine

Olpasiran

- In May 2022, we announced positive topline data from the Phase 2 OCEAN(a)-DOSE clinical study, evaluating olpasiran (formerly AMG 890) in adult patients with lipoprotein(a), or Lp(a), levels over 150 nmol/L and evidence of atherosclerotic cardiovascular disease (ASCVD). Olpasiran is a small interfering RNA (siRNA) designed to lower the body's production of apolipoprotein(a), a key component of Lp(a) that has been associated with an increased risk of cardiovascular events. In the double-blind placebo-controlled treatment period, olpasiran was administered up to 225 mg subcutaneously every 12 weeks to patients with a median baseline Lp(a) of approximately 260 nmol/L. These data demonstrated a significant reduction from baseline in Lp(a) of up to or greater than 90 percent at week 36 (primary endpoint) and week 48 (end of treatment period) for the majority of doses. No new safety concerns were identified during this treatment period.

Inflammation

TEZSPIRE

- In July 2022, our partner AstraZeneca plc announced that the Committee for Medicinal Products for Human Use of the EMA has recommended TEZSPIRE for marketing authorization in the European Union as an add-on therapy in patients 12 years and older with severe asthma who are inadequately controlled with high dose inhaled corticosteroids plus another medicinal product for maintenance treatment.

Business development

Proposed acquisition of ChemoCentryx, Inc.

- On August 4, 2022, Amgen announced its proposed acquisition of ChemoCentryx for $52.00 per share in cash, for a total transaction price of approximately $4.0 billion. ChemoCentryx is a biopharmaceutical company focused on orally-administered therapeutics to treat autoimmune diseases, inflammatory disorders and cancer. In the United States, ChemoCentryx markets TAVNEOS®, the first approved orally administered inhibitor of the complement 5a receptor as an adjunctive treatment for adult patients with severe active anti-neutrophil cytoplasmic autoantibody-associated vasculitis (ANCA vasculitis). The transaction is expected to close in the fourth quarter of 2022.

Selected financial information

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

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
Product sales						
U.S.	$ 4,446	$ 4,374	2 %	$ 8,483	$ 8,277	2 %
ROW	1,835	1,740	5 %	3,529	3,429	3 %
Total product sales	6,281	6,114	3 %	12,012	11,706	3 %
Other revenues	313	412	(24)%	820	721	14 %
Total revenues	$ 6,594	$ 6,526	1 %	$ 12,832	$ 12,427	3 %
Operating expenses	$ 4,418	$ 5,698	(22)%	$ 8,156	$ 9,470	(14)%
Operating income	$ 2,176	$ 828	*	$ 4,676	$ 2,957	58 %
Net income	$ 1,317	$ 464	*	$ 2,793	$ 2,110	32 %
Diluted EPS	$ 2.45	$ 0.81	*	$ 5.13	$ 3.65	41 %
Diluted shares	537	576	(7)%	544	578	(6)%

* Change in excess of 100%

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

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. For the second quarter 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 in Part II, Item 1A. Risk Factors of our Quarterly Report on Form 10-Q for the period ended March 31, 2022.

Other revenues decreased for the three months ended June 30, 2022, driven by lower revenue from COVID-19 antibody material and increased for the six months ended June 30, 2022, primarily driven by higher revenue from COVID-19 antibody material.

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

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is partially offset by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Further, while not designed to completely address foreign currency changes, our hedging activities seek to offset, in part, the effects of foreign currency exchange rate changes, both favorable and unfavorable, on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material for the three and six months ended June 30, 2022 and 2021.

Results of operations

Product sales

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

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
ENBREL	$ 1,051	$ 1,144	(8)%	$ 1,913	$ 2,068	(7)%
Prolia	922	814	13 %	1,774	1,572	13 %
Otezla	594	534	11 %	1,045	1,010	3 %
XGEVA	533	488	9 %	1,035	956	8 %
Aranesp	357	367	(3)%	715	722	(1)%
Neulasta	310	486	(36)%	658	968	(32)%
Repatha	325	286	14 %	654	572	14 %
KYPROLIS	317	280	13 %	604	531	14 %
Nplate	284	245	16 %	550	472	17 %
Other products	1,588	1,470	8 %	3,064	2,835	8 %
Total product sales	$ 6,281	$ 6,114	3 %	$ 12,012	$ 11,706	3 %

Future sales of our products will depend in part on the factors discussed below and in the following sections of this report: (i) Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview, and Selected Financial Information; and (ii) Part II, Item 1A. Risk Factors, and in the following sections of our Annual Report on Form 10-K for the year ended December 31, 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 Report on Form 10-Q for the period ended March 31, 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 June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
ENBREL — U.S.	$ 1,036	$ 1,113	(7)%	$ 1,879	$ 2,007	(6)%
ENBREL — Canada	15	31	(52)%	34	61	(44)%
Total ENBREL	$ 1,051	$ 1,144	(8)%	$ 1,913	$ 2,068	(7)%

The decrease in ENBREL sales for the three and six months ended June 30, 2022, was primarily driven by lower net selling price and lower unit demand.

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 June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
Prolia — U.S.	$ 611	$ 538	14 %	$ 1,193	$ 1,039	15 %
Prolia — ROW	311	276	13 %	581	533	9 %
Total Prolia	$ 922	$ 814	13 %	$ 1,774	$ 1,572	13 %

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

Otezla

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

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
Otezla — U.S.	$ 487	$ 423	15 %	$ 837	$ 789	6 %
Otezla — ROW	107	111	(4)%	208	221	(6)%
Total Otezla	$ 594	$ 534	11 %	$ 1,045	$ 1,010	3 %

The increase in global Otezla sales for the three months ended June 30, 2022, was driven by higher unit demand and favorable changes to estimated sales deductions, partially offset by lower net selling price.

The increase in global Otezla sales for the six months ended June 30, 2022, was primarily driven by higher unit demand and favorable changes to estimated sales deductions, partially offset by lower net selling price and unfavorable changes to inventory.

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 Note 13, Contingencies and commitments, to the condensed consolidated financial statements in this Quarterly Report.

XGEVA

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

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
XGEVA — U.S.	$ 391	$ 355	10 %	$ 759	$ 689	10 %
XGEVA — ROW	142	133	7 %	276	267	3 %
Total XGEVA	$ 533	$ 488	9 %	$ 1,035	$ 956	8 %

The increase in global XGEVA sales for the three and six months ended June 30, 2022, was primarily driven by higher net selling price and favorable changes to estimated sales deductions.

Aranesp

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

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
Aranesp — U.S.	$ 132	$ 135	(2)%	$ 269	$ 260	3 %
Aranesp — ROW	225	232	(3)%	446	462	(3)%
Total Aranesp	$ 357	$ 367	(3)%	$ 715	$ 722	(1)%

The decrease in global Aranesp sales for the three months ended June 30, 2022, was primarily driven by lower net selling price.

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

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.

Neulasta

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

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
Neulasta — U.S.	$ 263	$ 434	(39)%	$ 567	$ 855	(34)%
Neulasta — ROW	47	52	(10)%	91	113	(19)%
Total Neulasta	$ 310	$ 486	(36)%	$ 658	$ 968	(32)%

The decrease in global Neulasta sales for the three and six months ended June 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.

Repatha

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

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
Repatha — U.S.	$ 154	$ 143	8 %	$ 319	$ 282	13 %
Repatha — ROW	171	143	20 %	335	290	16 %
Total Repatha	$ 325	$ 286	14 %	$ 654	$ 572	14 %

The increase in global Repatha sales for the three and six months ended June 30, 2022, was driven by higher unit demand, partially offset by lower net selling price. 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, resulted in the decrease to 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; 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; and Part I—Note 13, Contingencies and commitments, to the condensed consolidated financial statements in this Quarterly Report.

KYPROLIS

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

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
KYPROLIS — U.S.	$ 213	$ 190	12 %	$ 409	$ 349	17 %
KYPROLIS — ROW	104	90	16 %	195	182	7 %
Total KYPROLIS	$ 317	$ 280	13 %	$ 604	$ 531	14 %

The increase in global KYPROLIS sales for the three and six months ended June 30, 2022, was driven by higher unit demand, partially offset by lower net selling price.

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.

Nplate

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

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
Nplate — U.S.	$ 156	$ 136	15 %	$ 312	$ 248	26 %
Nplate — ROW	128	109	17 %	238	224	6 %
Total Nplate	$ 284	$ 245	16 %	$ 550	$ 472	17 %

The increase in global Nplate sales for the three and six months ended June 30, 2022, was primarily driven by higher unit demand and net selling price.

Other products

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

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
MVASI — U.S.	$ 161	$ 206	(22)%	$ 329	$ 430	(23)%
MVASI — ROW	82	88	(7)%	158	158	— %
Vectibix — U.S.	96	92	4 %	181	171	6 %
Vectibix— ROW	111	147	(24)%	227	259	(12)%
EVENITY — U.S.	130	79	65 %	240	136	76 %
EVENITY— ROW	61	52	17 %	121	102	19 %
BLINCYTO — U.S.	77	62	24 %	156	127	23 %
BLINCYTO — ROW	62	46	35 %	121	88	38 %
EPOGEN — U.S.	136	130	5 %	256	255	— %
AMGEVITA — ROW	116	107	8 %	224	213	5 %
Aimovig — U.S.	88	82	7 %	186	148	26 %
Aimovig — ROW	4	—	NM	7	—	NM
Parsabiv — U.S.	71	37	92 %	128	83	54 %
Parsabiv — ROW	32	34	(6)%	61	67	(9)%
KANJINTI — U.S.	69	132	(48)%	149	262	(43)%
KANJINTI — ROW	16	24	(33)%	32	55	(42)%
LUMAKRAS — U.S.	51	9	*	99	9	*
LUMYKRAS — ROW	26	—	NM	40	—	NM
NEUPOGEN — U.S.	21	36	(42)%	44	54	(19)%
NEUPOGEN — ROW	16	15	7 %	31	31	— %
Sensipar — U.S.	5	4	25 %	9	4	*
Sensipar/Mimpara — ROW	15	20	(25)%	31	43	(28)%
Other — U.S.[1]	98	38	*	162	80	*
Other — ROW[1]	44	30	47 %	72	60	20 %
Total other products	$ 1,588	$ 1,470	8 %	$ 3,064	$ 2,835	8 %
Total U.S. — other products	$ 1,003	$ 907	11 %	$ 1,939	$ 1,759	10 %
Total ROW — other products	585	563	4 %	1,125	1,076	5 %
Total other products	$ 1,588	$ 1,470	8 %	$ 3,064	$ 2,835	8 %

NM = not meaningful

* Change in excess of 100%

[1] Other products include Corlanor, AVSOLA, TEZSPIRE, IMLYGIC and RIABNI as well as sales by Gensenta and Bergamo subsidiaries.

Operating expenses

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

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Change	2022	2021	Change
Operating expenses:						
Cost of sales	$ 1,510	$ 1,637	(8)%	$ 3,071	$ 3,127	(2)%
% of product sales	24.0 %	26.8 %		25.6 %	26.7 %	
% of total revenues	22.9 %	25.1 %		23.9 %	25.2 %	
Research and development	$ 1,039	$ 1,082	(4)%	$ 1,998	$ 2,049	(2)%
% of product sales	16.5 %	17.7 %		16.6 %	17.5 %	
% of total revenues	15.8 %	16.6 %		15.6 %	16.5 %	
Acquired in-process research and development	$ —	$ 1,505	NM	$ —	$ 1,505	NM
% of product sales	— %	24.6 %		— %	12.9 %	
% of total revenues	— %	23.1 %		— %	12.1 %	
Selling, general and administrative	$ 1,327	$ 1,384	(4)%	$ 2,555	$ 2,638	(3)%
% of product sales	21.1 %	22.6 %		21.3 %	22.5 %	
% of total revenues	20.1 %	21.2 %		19.9 %	21.2 %	
Other	$ 542	$ 90	*	$ 532	$ 151	*
Total operating expenses	$ 4,418	$ 5,698	(22)%	$ 8,156	$ 9,470	(14)%

NM = not meaningful

* Change in excess of 100%

Cost of sales

Cost of sales decreased to 22.9% and 23.9% of total revenues for the three and six months ended June 30, 2022, respectively, driven by lower COVID-19 antibody shipments, lower manufacturing costs and lower amortization expense from acquisition-related assets, partially offset by unfavorable product mix.

Research and development

The decrease in R&D expense for the three months ended June 30, 2022, was driven by lower marketed product support and lower expense resulting from acquisition-related activity, partially offset by higher spend in research and early pipeline.

The decrease in R&D expense for the six months ended June 30, 2022, was driven by lower marketed product support and lower expense resulting from acquisition-related activity, partially offset by higher late-stage development program spend and research and early pipeline spend.

Acquired in-process research and development

The decrease in Acquired IPR&D expense for the three and six months ended June 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 six months ended June 30, 2022, was primarily driven by lower spend for marketed products and lower expense resulting from acquisition-related activity.

Other

Other operating expenses for the three and six months ended June 30, 2022, consisted primarily of a loss on a nonstrategic divestiture. See Note 2, Acquisitions and divestitures. Other operating expenses for the three and six months ended June 30, 2021, consisted primarily of expenses related to cost saving initiatives.

Nonoperating expense/income and income taxes

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

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Interest expense, net	$ (328)	$ (281)	$ (623)	$ (566)
Other (expense) income, net	$ (317)	$ 11	$ (847)	$ 24
Provision for income taxes	$ 214	$ 94	$ 413	$ 305
Effective tax rate	14.0 %	16.8 %	12.9 %	12.6 %

Interest expense, net

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

Other (expense) income, net

The change in Other (expense) income, net, for the three and six months ended June 30, 2022, was primarily due to net losses recognized on our strategic equity investments in the current year compared with net gains recognized in the prior year and higher current year losses in connection with our BeiGene investment.

Income taxes

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

The Administration proposed and Congress is considering a variety of potentially significant changes to existing tax law. These changes, or others, could substantially increase 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 is expected to 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. While we expect these taxes to be partially offset by U.S. foreign tax credits, the U.S. Treasury has not yet issued guidance on whether the alternative fixed tax rate will be creditable under U.S. law.

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 will seek consolidation of 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*, 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):

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 7,183	$ 8,037
Total assets	$ 59,294	$ 61,165
Current portion of long-term debt	$ 817	$ 87
Long-term debt	$ 35,705	$ 33,222
Stockholders’ equity	$ 2,419	$ 6,700

Cash, cash equivalents and marketable securities

Our balance of cash, cash equivalents and marketable securities was $7.2 billion as of June 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 March 2022 and December 2021, the Board of Directors declared a quarterly cash dividend of $1.94 per share of common stock, which were paid on June 8, 2022 and March 8, 2022, respectively, an increase of 10% over quarterly cash dividend paid in each quarter in 2021. In August 2022, the Board of Directors declared a quarterly cash dividend of $1.94 per share of common stock, which will be paid on September 8, 2022 to all stockholders of record as of the close of business on August 18, 2022.

We also returned capital to stockholders through our stock repurchase program. During the six months ended June 30, 2022, we executed trades to repurchase $5.4 billion of common stock, including $5.1 billion of an initial purchase under the ASR agreements described below. As of June 30, 2022, $4.6 billion of authorization remained available under our stock repurchase program.

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 of stock remains to be delivered by the Dealers pending final settlement, which will be based on the daily volume-weighted average stock price of our common stock during the terms of the ASR agreements, less a discount and subject to adjustments pursuant to the terms and conditions of the ASR agreements. At settlement, which is scheduled to occur in the third quarter of 2022, the Dealers may be required to deliver additional shares of common stock to us, or under certain circumstances, we may be required to deliver shares of common stock or to make a cash payment, at our election, to the Dealers.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of June 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 June 30, 2022.

Cash flows

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

	Six months ended June 30,	
	2022	2021
Net cash provided by operating activities	$ 4,094	$ 4,035
Net cash (used in) provided by investing activities	$ (2,304)	$ 890
Net cash used in financing activities	$ (4,576)	$ (4,561)

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 six months ended June 30, 2022, increased primarily due to higher net income, after adjustments for noncash items, partially offset by the impact of working capital items.

Investing

Cash used in investing activities during the six months ended June 30, 2022, was primarily due to net cash outflows related to marketable securities activity of $1.9 billion and capital expenditures of $436 million. Cash provided by investing activities during the six months ended June 30, 2021, was primarily due to net cash inflows related to marketable securities activity of $2.9 billion, partially offset by the acquisition of Five Prime for $1.6 billion and capital expenditures of $351 million. We currently estimate 2022 spending on capital projects to be approximately $950 million.

Financing

Cash used in financing activities during the six months ended June 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, and the payment of dividends of $2.1 billion, partially offset by proceeds from the issuance of debt of $4.0 billion. Cash used in financing activities during the six months ended June 30, 2021, was primarily due to payments to repurchase our common stock of $2.5 billion and the payment of dividends of $2.0 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 six months ended June 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 June 30, 2022.

Management determined that as of June 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 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 and June 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 they involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Below we provide in supplemental form the material changes to our risk factors that occurred during the past quarter. Our risk factors disclosed in Part I, Item 1A, of our Annual Report on Form 10-K for the year ended December 31, 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 to attempt to lower drug prices. These include proposals that would enable the U.S. government to negotiate drug prices directly, limit drug reimbursement in Medicare and/or the commercial market based on reference prices, impose penalties if drug prices are increased at a rate faster than inflation or permit importation of drugs from Canada. Additional proposals would require a rebate to the government for any price increase in excess of the Consumer Price Index for All Urban Consumers and/or to shift some of the costs of these Medicare Part D reforms to manufacturers to offset the costs. Certain proposals focused on drug pricing 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. Since 2019, a number of Congressional committees debated drug pricing reform proposals, and in 2020, Amgen participated in House Oversight and Reform Committee hearings on drug pricing practices. In 2019, the Senate Finance Committee advanced a bill that would, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and/or D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries and require higher or additional manufacturer discounts in Medicare Part D. Additionally, in late 2019, a drug-pricing bill, H.R. 3, passed the House of Representatives and included provisions that, among other things, enabled direct price negotiations by the federal government on certain drugs, (with the maximum price paid by Medicare capped by prices derived from an international index), penalized failures to reach agreement with the government and required that manufacturers offer these negotiated prices to other payers. Provisions from H.R. 3 have

been incorporated and adapted into other proposed legislation, including the most recent reconciliation bill released by the Senate in July 2022, which included penalties if drug price benchmarks rise faster than inflation, Medicare price setting 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), and Part D redesign including a cap on beneficiary spending and a new manufacturer discount program. This framework remains in discussion with policymakers in Congress and the Administration. 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, 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 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, 2027. However, the future of this rule remains uncertain because, among other issues, it is subject to litigation and because a permanent repeal is being considered in other legislation.

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 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 announced it was withdrawing 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." Further, we expect continued significant focus on healthcare and similar drug pricing proposals for the foreseeable future, including proposals under which the government would set drug prices or limit drug reimbursement. 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. While the effective date for adding TEZSPIRE to the exclusion list has been deferred until further notice, this exclusion, if 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, 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. In this dynamic environment, particularly in light of the pressures on healthcare budgets as a result of the pandemic, we are unable to predict which or how many federal policy, legislative, regulatory, executive or administrative changes may ultimately be, or effectively estimate the consequences to our business if, enacted and implemented. However, to the extent that these or other federal government initiatives further decrease or modify the coverage or reimbursement available for our products, require that we pay increased rebates or shift other costs to us, limit or affect our decisions regarding the pricing of or otherwise reduce the use of our U.S. products, or limit our ability to offer co-pay 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. A number of states have adopted, and many other states are considering, drug importation programs or other new pricing actions, including proposals designed to require biopharmaceutical manufacturers to publicly report proprietary pricing information, limit price increases or place a maximum price ceiling or cap on biopharmaceutical products. Existing and proposed state pricing laws have added complexity to the pricing of drugs and may already be affecting industry pricing decisions. For example, a California law, the constitutionality of which is currently being challenged, purports to require 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. 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. 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 copay or coinsurance obligations and more significant limitations on patients' use of manufacturer commercial copay 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 has caused commercial payers to more widely adopt copay 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. 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 EMA'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.

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

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

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes can 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, and such tax authorities (including the IRS) are becoming more aggressive in their audits and are particularly focused on such matters. In 2017, we received 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 administrative 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 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.

In 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015, also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010–2012. 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 and asserts penalties.

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 will seek consolidation of the two periods into one case in the U.S. Tax Court.

We are currently also under examination by the IRS for the years 2016, 2017 and 2018 with respect to issues similar to those for the 2010 through 2015 period. In addition, we are under examination by a number of state and foreign tax jurisdictions.

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

See Part I, Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations, Income Taxes, and Part I—Note 4, Income taxes, to the condensed consolidated financial statements.

Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities and changes in applicable tax laws, regulations or administrative interpretations thereof. The 2017 Tax Act is complex and a large volume of regulations and guidance has been issued and could be subject to different interpretations. We could face audit challenges to our application of the 2017 Tax Act. The Administration proposed and Congress is considering a variety of potentially significant changes to existing tax law. These changes, or others, could substantially increase 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 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 is expected to 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. While we expect these taxes to be partially offset by U.S. foreign tax credits, the U.S. Treasury has not yet issued guidance on whether the alternative fixed tax rate will be creditable under U.S. law.

Changes to existing tax law in the United States, the U.S. territory of Puerto Rico, or other jurisdictions, including the changes and potential changes discussed above, could result in tax increases where we do business and could have a material adverse effect on the results of our operations.

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

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

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

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

During the three months ended June 30, 2022, we had one outstanding stock repurchase program, under which the repurchase activity was as follows:

Period	Total number of shares purchased [1]	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
April 1 - 30	—	—	—	4,579,263,848
May 1 - 31	—	—	—	4,579,263,848
June 1 - 30	—	—	—	4,579,263,848
Total	—		—	

[1] As part of the stock repurchase program, the Company entered into ASR agreements with three third-party financial institutions (Dealers) in February 2022. Under 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. Approximately $0.9 billion of stock was held back by the Dealers pending final settlement of the ASR agreement, which will be based on the volume-weighted average stock price of the Company's common stock during the term of the ASR agreements, less a discount and subject to adjustments pursuant to the terms and conditions of the ASR agreements. At settlement, which is scheduled to occur in the third quarter of 2022, the Dealers may be required to deliver additional shares of common stock to the Company, or under certain circumstances, the Company may be required to deliver shares of common stock or to make a cash payment, at its election, to the Dealers.

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.)
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.6	Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.7	Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.8	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.9	Officers' Certificate of Amgen Inc., dated May 30, 2007, including form of the Company's 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
4.10	Officers' Certificate of Amgen Inc., dated May 23, 2008, including form of the Company's 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)
4.11	Officers' Certificate of Amgen Inc., dated January 16, 2009, including form of the Company's 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)

Exhibit No.	Description
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.)
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.)

Exhibit No.	Description
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.)
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.)
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.)

Exhibit No.	Description
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.)
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.)

Exhibit No.	Description
10.30	Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.31	Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.32	Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.33	Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
10.34	Side Letter Regarding Collaboration Agreement and Stivarga Agreement, dated February 13, 2020, by and between Onyx Pharmaceuticals, Inc. and Bayer HealthCare LLC. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)
10.35	Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.36	Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.37	Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.38	Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.39	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.)
10.40	Collaboration Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene Switzerland GmbH, a wholly-owned subsidiary of BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.41*	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.)
10.42	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.)
10.43	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.)
10.44	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.)

Exhibit No.	Description
10.45	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.)
10.46*	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.)
10.47*	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.)
10.48	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.)
10.49	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.)
10.50	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.)
10.51	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.)
10.52	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.
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: August 4, 2022

By: /S/ PETER H. GRIFFITH

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

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.

FIRST AMENDMENT TO COLLABORATION AGREEMENT

This Amendment to the Collaboration Agreement ("Amendment") is entered into as of April 20, 2022 (the "Amendment Effective Date") by and among Amgen Inc., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799 ("Amgen"), BeiGene Switzerland GmbH, a Swiss corporation with a principal place of business at Aeschengraben 27, 4051 Basel, Switzerland ("BeiGene"), and BeiGene, Ltd., a Cayman Islands exempted company incorporated with limited liability with its registered offices c/o Mourant Governance Services (Cayman) Limited, 94 Solaris Avenue, P.O. Box 1348, Grand Cayman KY1-1108, Cayman Islands ("BeiGene Parent"). BeiGene and Amgen are sometimes referred to herein individually as a "Party" and collectively as the "Parties." This Amendment amends that certain Collaboration Agreement (the "Agreement"), entered into as of October 31, 2019, by and between Amgen and BeiGene and, solely with respect to Section 13.6 thereof, BeiGene Parent. Capitalized terms used but not defined herein have the meanings given to them in the Agreement.

RECITALS

WHEREAS, the Agreement contains certain terms and conditions relating to the financial responsibilities of the Parties in connection with the development and commercialization of certain Amgen proprietary Products for the treatment of oncology-related diseases and conditions; and

WHEREAS, the Parties desire to amend the Agreement upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, the Parties, intending to be legally bound hereby, do agree as follows:

AGREEMENT

1. Amendment to Section 1.48 of the Agreement. Section 1.48 of the Agreement is hereby amended and replaced in its entirety as follows:

   "Section 1.48 "Costs" means both internal and external costs and expenses (including the cost of allocated FTEs at the FTE Rate and Sales Force FTEs at the Sales Force FTE Rate). [*]"

2. New Section 1.170. The following is hereby inserted as a new Section 1.170 of the Agreement:

   "Section 1.170 "Hainan Bo Ao" shall mean Pilot Zone in the Hainan province where Bo Ao Product may be stored and then imported into the Collaboration Territory with a patient application prior to Regulatory Approval for the Bo Ao Product in the Collaboration Territory."

3. New Section 1.171. The following is hereby inserted as a new Section 1.171 of the Agreement:

   "Section 1.171 "Bo Ao Support Costs" means all actual and, if reasonably practicable, documented costs incurred by Amgen and/or its Affiliates and pre-approved pursuant to the Supply Agreement, if applicable, [*]"

4. New Section 1.172. The following is hereby inserted as a new Section 1.172 of the Agreement:

   "Section 1.172 "Product Team" means, for any Product [*]."

5. New Section 1.173. The following is hereby inserted as a new Section 1.173 of the Agreement:

"Section 1.173 "Work Package Team" means, for any Product [*]."

6. Amendment to Section 7.1.2 of the Agreement. The following text is hereby inserted as a new Section 7.1.2(d), Section 7.1.2(e), Section 7.1.2(f), and Section 7.1.2(g), respectively, of the Agreement: [*]

7. Amendments to Section 7.2 of the Agreement.

a. The first paragraph of Section 7.2 (Profit Sharing) of the Agreement is hereby amended and replaced in its entirety as follows:

"Section 7.2 Profit Sharing.

(a) Prior to the Transition Date designated by the Joint Steering Committee (generally the second Launch Readiness Review for a Product) for an In-Line Product (the "Transition Date") pursuant to Section 3.1.1 (Transition and Development of Products) and Section 5.1.2(b) (Initial In-Line Product Transition), [*] set forth in the definition of "Commercialization and Related Costs." The Joint Steering Committee has designated the Transition Date for each In-Line Product as follows: XGEVA®, [*]; BLINCYTO®, [*]; and Kyprolis®, [*].

For the avoidance of doubt, [*] from Amgen to BeiGene pursuant to Section 3.1.1 (Transition and Development of Products) and Section 5.1.2(b) (Initial In-Line Product Transition).

(b) [*] set forth in the definition of "Commercialization and Related Costs" for each Pipeline Product until [*] prior to the anticipated launch date for such Pipeline Product (such date to be designated for each Pipeline Product by the Joint Alliance Committee and subject to adjustment by the Joint Alliance Committee in the event the anticipated launch date changes) (such date, the "Initiation Date").

(c) The Parties will share in Profits generated by Products in the Collaboration Scope: (i) with respect to In-Line Products, beginning on [*] and ending upon [*] for such In-Line Product; (ii) with respect to Pipeline Products, beginning on [*] and ending upon [*] for such Pipeline Product; and (iii) for such longer period as set forth in Section 5.1 for each Retained In-Line Product and each Retained Pipeline Product (i.e., for so long as such Retained In-Line Product or Retained Pipeline Product, as applicable, is sold in the Collaboration Territory); in each case as follows:"

b. Section 7.2.3 (FTE Rate) of the Agreement is hereby amended and restated in its entirety as follows:

"Section 7.2.3. FTE Rate.

(a) The FTE Rate used for calculation of Costs pursuant to this Article VII (Financial Consideration) with respect to any activity will be the relevant FTE Rate for [*] in which such activity was undertaken.

(b) Effective as of [*], the Parties agree that the Costs (calculated using the development FTE Rate (as defined in Section 1.72(i)) or commercial FTE Rate (as defined in Section 1.72(ii)), as applicable) of FTEs performing Product Team/Work Package Team strategy activities (i.e. Support to advise

on the China specific aspects of the Global Development Plan) for Pipeline Products incurred by the Parties or their respective Affiliates: (i) prior to Regulatory Approval, in accordance with the Development Plan and Development Budget will be deemed Amgen Pipeline Product Global Development Costs and subject to Global Development Cost-Share Payments in accordance with Section 7.1.2 (Global Development Cost Share) and (ii) after Regulatory Approval (including strategy activities for new indications or label expansion after Regulatory Approval), in accordance with the Commercialization Plan and Commercialization Budget, will be deemed to be Commercialization and Related Costs and included in the collaboration profit sharing pursuant to Section 7.2 (Profit Sharing). The Product Team and Work Package Team FTEs will be initially set, and shall in no event exceed, [*] to support the Pipeline Products. The table below sets out the 2021 baseline budget for Product Team/Work Package Team strategy FTEs based on the Pipeline Product portfolio as of the Amendment Effective Date. [*]

(c) The Product Team and Work Package Team FTE allocation for Pipeline Products will be adjusted by Amgen [*] based on relevant factors, [*]."

c. The following is hereby inserted as a new Section 7.2.8 of the Agreement:

"Section 7.2.8 Hainan Bo Ao Cost-Share Matters. Notwithstanding anything to the contrary in this Agreement, with respect to the AMG 510 (also known as sotorasib or LUMAKRAS®) Product (the "Bo Ao Product"), the Parties desire to initiate the Profit-sharing arrangement set forth in Section 7.2 prior to applicable Initiation Date, subject to the following terms and conditions:

(a) *Commercialization and Related Costs*. Prior to the applicable Initiation Date, costs (including Costs for outside services and expenses (e.g., consultants, agency fees, etc.)) for the following activities shall be considered "Commercialization and Related Costs" for purposes of determining "Amgen Costs" or "BeiGene Costs," as applicable:

(i) [*];

(ii) Medical Affairs Activities Costs incurred in connection with Hainan Bo Ao in or for the Collaboration Territory prior to commercialization and during commercialization;

(iii) all Costs incurred by the Parties or their respective Affiliates associated with any recalls of the Bo Ao Product in the Collaboration Scope and in or for the Collaboration Territory;

(iv) all Costs incurred by the Parties or their respective Affiliates with respect to product liability claims for the Bo Ao Product in the Collaboration Scope in the Collaboration Territory;

(v) all Costs incurred by the Parties or their respective Affiliates associated with any returns and withdrawals of the Bo Ao Product in the Collaboration Scope in the Collaboration Territory;

(vi) any Third Party IP Payments to the extent not already included in Manufacturing Actual Costs; and

(viii) all unrecovered Indirect taxes, including, for the avoidance of doubt, unrecovered VAT surcharge, incurred by either Party arising with respect to payments to be made under Section 7.2.7 (Calculation of Collaboration Profits). [*]

Commercialization and Related Costs for purposes of this Section 7.2.8 shall not include [*] or any Cost subject to an indemnification obligation under Article XIII.

(b) *Manufacturing Actual Costs*. The Manufacturing Actual Costs incurred with respect to the Bo Ao Product in connection with Hainan Bo Ao shall be deemed "Amgen Costs" for purposes of the calculations set forth under Section 7.2 (Profit Sharing).

(c) *Net Revenues.* Net Revenues from the sale or transfer for value of the Bo Ao Product in Hainan Bo Ao shall be considered "Net Revenues" for purpose of Section 7.2 (Profit Sharing).

(d) *Support Costs*. Bo Ao Support Costs incurred with respect to Bo Ao Product in connection with Hainan Bo Ao shall be deemed "Amgen Costs" for purposes of the calculations set forth under Section 7.2 (Profit Sharing)."

8. Amendment to Section 7.9 of the Agreement. Section 7.9 (Overruns) of the Agreement is hereby supplemented and amended by adding the following at the end of the existing Section 7.9:

"Without limiting the foregoing, the Parties further agree as follows:

(a) While the final overrun calculation is based on annual amounts, the Parties agree to perform quarterly assessments of cost variances for the Overrun Categories shown below, recognizing that both Parties have quarterly reporting requirements.

(b) In any given calendar quarter, the quarterly profit share and development cost share calculations will reflect up to a maximum of [*] of the planned amounts of the "Overrun Categories" (with an exception for materiality described in Section 7.9(e) below).

(c) To the extent costs exceed [*] of the budgeted amount in a given calendar quarter, the following shall apply: The Parties agree that they will track variances above [*] of the planned amount into subsequent calendar quarters, to comply with the annual nature of the cost overage calculation in this Section 7.9. [*] If, at a later time, joint approval is obtained from each Party's finance representative to the JAC for additional activities and related spending beyond the [*] cap, an adjustment will be made in the subsequent period.

(d) To the extent costs are below budget in a given calendar quarter, actual variances resulting in underspend will be reimbursable in a subsequent period to the extent costs are for a pre-agreed upon activity that had a timing difference and the rationale for the variance is communicated, along with the rationale for why the activity/spend will be performed in a subsequent period. The Parties may agree to a new activity to take the place of the activity that did not occur and the costs of such activity will be reimbursed if under the [*] expense cap, unless otherwise agreed. Agreement will be obtained by each Party's finance representatives to the JAC.

(e) The Parties have agreed to a US$[*] dollar threshold for calendar quarter reconciliation of cost overruns, to eliminate the inefficient analysis of greater than [*] variance for smaller dollar amount categories. [*]

(f) Costs will be evaluated for overrun in the following manner: [*]

(g) The baseline for the overrun calculation pursuant to this Section 7.9 will be the most recently approved Global Development Budget or Commercialization Budget, as applicable."

9. New Section 7.12 of the Agreement. The following is hereby inserted as a new Section 7.12 of the Agreement:

"Section 7.12 Additional Cost-Share Matters. The Parties expect that from time-to-time one Party may perform activities that are the responsibility of the other Party or a Party may request that the other Party provide services or conduct activities that are not contemplated by the Agreement. In these instances, if the JAC approves such activities and the budget for such activities, the Party performing the activity for the benefit of the other Party shall be reimbursed for the reasonable costs of providing such services or conducting such activities. Such costs shall be documented in writing and the Party providing such service shall be reimbursed quarterly to the Party performing such service concurrently with the Compensating Payment made pursuant to Section 7.2.7 (Calculation of Collaboration Profits). As of the Effective Date, the Parties have agreed that Amgen shall be reimbursed for the following activities as set forth below: [*]"

10. Supply Price Schedule. The Supply Price Schedule is hereby amended to include the following as a new row:

[*]	[*]

11. Miscellaneous.

d. Except as specifically amended above, the Agreement shall continue to be in full force and effect.

e. This Amendment and its effect are subject to and shall be construed and enforced in accordance with the laws of the State of New York, U.S.A.

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

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Effective Date.

AMGEN INC.

/s/ Rachna Khosla

Name: Rachna Khosla
Title: SVP Business Development

BEIGENE SWITZERLAND GMBH

/s/ Beatriz Martinez-Lahuerta

Name: Beatriz Martinez-Lahuerta
Title: Assistant General Counsel, Head of Legal, Europe & New Markets

BEIGENE, LTD.

/s/ Angus Grant

Name: Angus Grant
Title: Senior Vice President, Chief Business Executive

EXHIBIT 10.46

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.

Collaboration Agreement

by and between

Amgen Inc.

and

AstraZeneca Collaboration Ventures, LLC

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Schedules

Collaboration Agreement

This Collaboration Agreement (this *"Agreement"*) is entered into as of the 30th day of March, 2012 (the *"Effective Date"*) by and between Amgen Inc., a Delaware corporation with a place of business at One Amgen Center Drive, Thousand Oaks, California 91320 (*"Amgen"*), and AstraZeneca Collaboration Ventures, LLC, a Delaware limited liability company with a place of business at 1800 Concord Pike, Wilmington, Delaware 19850 (*"Partner"*). Amgen and Partner are sometimes referred to herein individually as a *"Party"* and collectively as the *"Parties"*. AstraZeneca Pharmaceuticals LP, the parent corporation of Partner (*"AstraZeneca"*), [*] is a party to this Agreement [*].

Recitals

WHEREAS, Amgen is a global biopharmaceutical company that researches, develops, manufactures and commercializes novel therapeutics to treat grievous illness;

WHEREAS, Amgen has developed certain proprietary Products (as defined below) for the treatment of certain diseases and conditions; and

WHEREAS, Amgen and Partner desire to collaborate, and share certain expenses and revenues, with respect to the development, manufacture and commercialization of the Products as set forth in more detail herein.

NOW, THEREFORE, in consideration of the premises and the mutual promises set forth herein, and intending to be legally bound, the Parties agree as follows:

1. DEFINITIONS

1.1. *"Access and Pricing Plan"* means the country specific plan for a Product approved by the JSC that sets forth the proposed price, target population and reimbursement target.

1.2. *"Affiliate"* means, with respect to a Party, any Person which controls, is controlled by or is under common control with such Party. For purposes of this definition only, "control" means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the securities entitled to be voted generally or in the election of directors of such Person, or by contract or otherwise. For clarity, Kirin-Amgen, Inc. shall not be considered an Affiliate of Amgen. Notwithstanding the foregoing, for the purposes of Article 9 (Distracting Products) and Section 1.51 (*"Distracting Transaction"*) only, [*].

1.3. *"Agreement"* has the meaning set forth in the Preamble.

1.4. *"Alliance Manager"* has the meaning set forth in Section 2.9 (Alliance Managers).

1.5. *"AMG157 Data Package"* has the meaning set forth in Section 14.2 (Termination for Convenience).

1.6. *"AMG157 Termination Event"* has the meaning set forth in Section 14.2 (Termination for Convenience).

1.7. *"AMG827 Territory"* means Australia, Canada, Mexico, New Zealand, the United States (its territories and possessions), all European countries, including those listed in Column 1 of the AMG827 Territory Schedule attached hereto, all Central and South American countries, including those listed in Column 2 of AMG827 Territory Schedule attached hereto, and those certain African and Middle East countries listed in Column 3 of AMG827 Territory Schedule attached hereto.

1.8. *"Amgen"* has the meaning set forth in the Preamble.

1.9. *"Amgen Costs"* has the meaning set forth in Section 7.2.2 (Amgen Costs).

1.10. *"Amgen Distribution Countries"* means those countries listed on the Amgen Distribution Countries Schedule.

1.11. *"Amgen Housemarks"* means (i) the corporate logo of Amgen, (ii) the trademark "Amgen", (iii) any other trademark, trade name or service mark (whether registered or unregistered) containing the word "Amgen", and (iv) any other trademark or service mark associated with goods or services of Amgen or its Affiliates, but excluding the Product Trademarks and trademarks, trade names or service marks associated with goods or services outside the scope of this Agreement; and all intellectual property rights residing in any of the foregoing.

1.12. *"Amgen Indemnitees"* has the meaning set forth in Section 13.1 (Indemnity by Partner).

1.13. *"Amgen Intellectual Property"* means any Know-How, Patent, electronic media registrations (including domain names, usernames, websites, blogs and the like), or Copyright controlled by Amgen or its Affiliates that (i) as of the Effective Date is being used in connection with the research and development of any of the Products, or (ii) is used (but is not generated or conceived) during the Term by either Party or its Affiliates in the performance of this Agreement. Amgen Intellectual Property specifically excludes Program Intellectual Property.

1.14. *"Amgen Sales Force Costs"* means the allocable share of Amgen's or its Affiliates' sales force costs for sales representatives that Detail Products in the Collaboration Scope in accordance with this Agreement, calculated in accordance with Section 7.2.11 (Calculation of Sales Force Costs).

1.15. *"Anti-Corruption Laws"* means the US Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

1.16. *"Applicable Laws"* means, individually and collectively, any federal, state, local, national and supra-national laws, treaties, statutes, ordinances, rules and regulations, including any rules, regulations, guidance, guidelines or requirements having the binding effect of law of national securities exchanges, automated quotation systems or securities listing organizations, Governmental Authorities, courts, tribunals, agencies other than Governmental Authorities, legislative bodies and commissions that are in effect from time to time during the Term and applicable to a particular activity hereunder.

1.17. *"Assisting Party"* has the meaning set forth in Section 13.4 (Defense of Third Party Claims).

1.18. *"AstraZeneca"* has the meaning set forth in the Preamble.

1.19. *"Audited Party"* has the meaning set forth in Section 8.4 (Audits).

1.20. *"Auditing Party"* has the meaning set forth in Section 8.4 (Audits).

1.21. *"Brand Plan"* means the global, cross-functional commercialization plan for a Product approved by the JSC, including any applicable Global Payer Plan and country specific Access and Pricing Plan.

1.22. *"Bundle"* means any Product sold together with another pharmaceutical compound for a single price, including combination products or more than one product sold together.

1.23. *"cGMP"* has the meaning set forth in the applicable Quality Agreement.

1.24. *"Collaboration Review Committee"* or *"CRC"* means the review committee established pursuant to Article 2 (Scope and Governance).

1.25. *"Collaboration Profit (Loss)"* has the meaning set forth in Section 7.2.8 (Calculation of Profit (or Loss)).

1.26. *"Collaboration Scope"* means, with respect to a particular Product, any and all uses of such Product in the applicable Collaboration Territory.

1.27. *"Collaboration Territory"* means the world, except for the Excluded Territory for AMG557 and AMG827.

1.28. *"Commercialization Budget"* has the meaning set forth in Section 2.4.1.3. An initial Commercialization Budget for each Product will be approved by the JSC not later than three (3) months after initiation of the first Phase 3 Trial for such Product.

1.29. *"Commercial Lead"* has the meaning set forth in Section 5.2 (Commercial Lead).

1.30. *"Commercially Reasonable Efforts"* means, with respect to activities of a Party related to a Product under this Agreement, the efforts and resources typically used by that Party in the conduct of such activities with respect to products of comparable market potential, taking into account all relevant factors including, as applicable, stage of development, efficacy and safety relative to competitive products in the marketplace, actual or anticipated Governmental Authority approved labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), and cost and likelihood of obtaining Regulatory Approval. For purposes of clarity, Commercially Reasonable Efforts will be determined on a country-by-country basis within the Collaboration Territory, and it is anticipated that the level of effort may be different for different countries and may change over time, reflecting changes in the status of a Product and the country(ies) involved.

1.31. *"Competing Product"* has the meaning set forth in Section 5.9 (Competing Products).

1.32. *"Confidential Information"* has the meaning set forth in Section 11.1 (Confidentiality; Exceptions).

1.33. *"Continued Development Meeting"* means on a Product-by-Product basis, a meeting of the JSC to be held promptly following the completion of the Stage 1 Clinical Trial(s) for such Product, in which the JSC will discuss plans for the next phase of development of each such Product.

1.34. *"Contract Interest Rate"* means [*], plus the thirty (30) day U.S. Dollar LIBOR rate effective for the date that payment was due, as published by The Wall Street Journal, Eastern U.S. Edition, on the date such payment was due (or, if unavailable on such date, the first date thereafter on which such rate is available), or, if lower, the maximum rate permitted by Applicable Law.

1.35. *"Copyright"* means all right, title, and interest in and to all copyrightable works and any copyright registration or corresponding legal right.

1.36. *"Costs"* means both internal and external costs and expenses (including the cost of allocated FTEs at the FTE Rate).

1.37. *"Country Plans"* has the meaning set forth in Section 5.1 (Allocation of Commercial Responsibility).

1.38. *"Critical Matters"* means (A) all decisions made by the CRC, JSC and JPTs that, in the reasonable opinion of either Party, are likely to have any of the following impacts: (i) [*] under a Development Plan or Brand Plan; (ii) a change to a Development Plan or Brand Plan that results in the lesser of (a) an increase of [*] or more (*provided*, that such amount is at least [*]) and (b) [*] or more, in each case, to the then-current budgeted amount of Development Costs and/or General Costs for any specific calendar year under the applicable Development Budget, Operations Budget or Commercialization Budget or the amounts estimated under Sections 7.2.1 (Partner Costs) and 7.2.2 (Amgen Costs); (iii) a change to a Development Plan or Brand Plan

that results in a decrease of [*] (*provided*, that such amount is at least [*]) or more to the then-current budgeted amount of Development Costs and/or General Costs for any specific calendar year under the applicable Development Budget, Operations Budget or Commercialization Budget or the amounts estimated under Sections 7.2.1 (Partner Costs) and 7.2.2 (Amgen Costs); or (iv) a change to a Development Plan (including any plans with respect to a contemplated Regulatory Approval set forth therein) or Brand Plan that would, based upon [*], result in [*] of a Product for any specific calendar year under the applicable Development Plan or Brand Plan; (B) agreement of the initial Commercialization Budget for each Product; (C) agreement of the initial Brand Plan (or material updates thereto reflecting the launch of a new indication), Global Payer Plan and any Access and Pricing Plan for each Product; and (D) deadlocks with respect to the approval of an annual Development Budget, Operations Budget or Commercialization Budget as provided for under Section 7.7 (Budget Deadlocks).

1.39. *"Defending Party"* has the meaning set forth in Section 13.4 (Defense of Third Party Claims).

1.40. *"Designated Amgen Activities"* means those development, regulatory, manufacturing, access and commercial activities for which Amgen is responsible pursuant to this Agreement, including such activities allocated to it by any of the committees and teams established under this Agreement.

1.41. *"Designated Partner Activities"* means those development, regulatory, manufacturing, access and commercial activities for which Partner is responsible pursuant to this Agreement, including such activities allocated to it by any of the committees and teams established under this Agreement.

1.42. *"Designated Regulatory Party"* has the meaning set forth in Section 3.2.1 (Designated Regulatory Party).

1.43. *"Detail"* means an interactive face-to-face visit by a sales representative with a medical professional having prescribing authority or who is able to influence prescribing decisions, within the target audience during which approved uses, safety, effectiveness, contraindications, side effects, warnings or other relevant characteristics of a pharmaceutical product are discussed in an effort to increase prescribing preferences of a pharmaceutical product for its approved uses. Detail includes First Position Details, Second Position Details and Other Details. Details will not include (i) activities conducted by medical support staff (such as medical science liaisons) or (ii) E-details, activities conducted at conventions or similar gatherings and activities performed by market development specialists, managed care account directors and other personnel not performing face-to-face sales calls or not specifically trained with respect to a pharmaceutical product. *"Detailing"* means the act of performing Details and to *"Detail"* means to perform Details.

1.44. *"Development Budget"* has the meaning set forth in Section 2.4.1.1. The initial Development Budgets will be agreed in writing by the Parties as soon as reasonably practicable on or after the Effective Date.

1.45. *"Development Costs"* means with respect to all Products:

1.45.1. all Costs associated with obtaining, maintaining and renewing Regulatory Filings and Regulatory Approvals pertaining to a Product in accordance with the applicable Development Plan;

1.45.2. all Costs incurred by the Parties or their respective Affiliates in performing activities designated to the Parties under the applicable Development Plan, as applicable (including the Costs of clinical trials and related support to obtain marketing approval for a Product and other lifecycle management activities as well as Phase 4 Trials, development of related devices, observational research

and any economic value evidence generation in support of reimbursement activities such as health technology assessment submissions);

1.45.3. all manufacturing Costs not otherwise included in Manufacturing Standard Cost or Manufacturing Actual Costs, including stability testing and other CMC support costs for such Products, Costs relating to the development of manufacturing processes, scale-ups, validations and technology transfers for Products;

1.45.4. for any clinical supply of Products, (i) the Manufacturing Standard Cost, if it is manufactured in the Manufacturing Lead's (or its designee's) clinical manufacturing facility, or (ii) all Manufacturing Actual Costs, if it is manufactured in the Manufacturing Lead's (or its designee's) non-clinical (i.e., commercial) manufacturing facility;

1.45.5. all Costs for other materials (such as non-Party comparator drugs and placebo) obtained for use in clinical trials of or related to a Product; and

1.45.6. all Costs associated with engineering, conformance, or other manufacturing activities required to achieve commercial scale production of a Product, CMC filing requirements, and the like not otherwise included in Manufacturing Actual Costs for such Product.

All to the extent incurred after the Effective Date. For clarity, Development Costs are exclusive of and do not include General Costs. Except to the extent already included in overhead, Development Costs shall not include either Party's Costs to the extent they solely relate to legal, accounting, finance or alliance management activities associated with overseeing execution of and compliance with this Agreement.

1.46. *"Development Lead"* has the meaning set forth in Section 3.1.2 (Development Lead).

1.47. *"Development Plan"* means the plan approved by the JSC for each Product (which plan will be updated annually and will cover a period of at least [*] years) covering: (i) the research and development (including Phase 4 Trials) of the Products in the Collaboration Scope, including observational research and payer evidence generation including economic value; (ii) the preparation and submission of Regulatory Filings; and (iii) the obtaining, maintenance or expansion of Regulatory Approvals of the Products in the Collaboration Scope. The initial Development Plans covering calendar years [*] will be agreed in writing by the Parties as soon as reasonably practicable on or after the Effective Date.

1.48. *"Distracting Product"* means, with respect to a given Product, any product, [*], directed at [*] the Product Target or any Distracting Target [*]. For clarity, a [*] antibody that binds to [*] shall be a Distracting Product unless the Parties agree otherwise.

1.49. *"Distracting Program"* means the clinical development, manufacture or commercialization (including Detailing, selling, promoting or distributing) of any Distracting Product.

1.50. *"Distracting Target"* has the meaning set forth on the Distracting Product Schedule.

1.51. *"Distracting Transaction"* means any transaction entered into by a Party or its Affiliates on or after the Effective Date whereby a Third Party that is engaged in a Distracting Program becomes an Affiliate of a Party or any of its Affiliates.

1.52. *"Distracting Transaction Party"* has the meaning set forth in Section 9.3.3 (Inclusion).

1.53. *"Distribution Party"* has the meaning set forth in Section 4.4 (All Sales by Distribution Party).

1.54. *"Divest"* means, with respect to any Distracting Program, the sale, exclusive license or other transfer of all right, title and interest in and to such Distracting Program, including technology, intellectual property and other assets materially relating thereto, to a Third Party, without the retention or reservation of any rights or interest (other than an economic interest, reversion rights or other similar rights typical of a licensor in an exclusive license agreement) in such Distracting Program by such Party or its Affiliates.

1.55. *"Early Stage Programs"* has the meaning set forth in Section 4.1 (Allocation of Manufacturing Responsibility).

1.56. *"Effective Date"* has the meaning set forth in the Preamble.

1.57. *"Europe"* means those countries, nations, states or other territories under the jurisdiction of the European Medicines Agency (or any successor agency thereto), as such jurisdiction may change from time to time, and Iceland, Liechtenstein, Norway and Switzerland.

1.58. *"Excluded Territory"* means (i) with respect to AMG557, Japan, and (ii) with respect to AMG827, all countries not included within the AMG827 Territory.

1.59. *"Excluded Territory Agreement"* means (i) in relation to AMG827, the AMG827 Technology Transfer Agreement by and among Kyowa Hakko Kirin Co., Ltd., Amgen and Kirin-Amgen, Inc., the Research, Development and Technology Disclosure Agreement: AMG827 by and among Kyowa Hakko Kirin Co., Ltd., Amgen and Kirin-Amgen, Inc., and the AMG827 License Agreement between Kirin-Amgen, Inc., all dated October 29, 2010 and (ii) in relation to AMG557, means the License Agreement by and between Amgen and Takeda Pharmaceutical Company Limited dated February 1, 2008, in each case as the same have been amended and may be amended from time to time hereafter in accordance with terms of this Agreement.

1.60. *"First Position Detail"* means a Detail in which the applicable pharmaceutical product is Detailed before any other product and/or the predominant portion of time is devoted to the Detailing of such pharmaceutical product.

1.61. *"Force Majeure"* has the meaning set forth in Section 15.7 (Force Majeure).

1.62. *"FTE"* means, with respect to a person (other than an employee that Details a Product), the equivalent of the work of one (1) employee full time for one (1) year (consisting of at least a total of [*] weeks or [*] hours per year (excluding vacations and holidays)). Overtime, and work on weekends, holidays and the like [*] be counted [*] toward the number of hours that are used to calculate the FTE contribution. For an employee that Details a Product, FTEs will be calculated as set forth in Section 7.2.11 (Calculation of Sales Force Costs).

1.63. *"FTE Rate"* means, for the period commencing on the Effective Date until such time as the Parties agree otherwise, (i) [*] for activities conducted in the U.S., and (ii) for all other geographic locations [*] multiplied by a cost of living adjustment between the U.S. and such other geographic location as set forth in the then most current edition of [*] (or in the event such geographic location is not listed, the nearest listed geographic location that is most comparable to such non-listed geographic location). The FTE Rate will be increased by [*]. The FTE Rate shall include costs of salaries, benefits, supplies, other employee costs, facility costs, depreciation and supporting general and administration allocations.

1.64. *"GAAP"* means the then-current generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity or other entity generally recognized as having the right to establish such principles in the United States, in each case consistently applied.

1.65. *"General Costs"* means with respect to all Products:

1.65.1. all Costs, other than Amgen Sales Force Costs and Partner Sales Force Costs, associated with activities related to the commercialization of Products, including: sales, pricing, access, coverage (including risk sharing arrangements), reimbursement, presentation, purchase of ancillary items or devices, contracting, launch timing, distribution, marketing messaging, product positioning, development of training materials, sales tracking and auditing, market research and product usage surveys, provision of medical affairs support staff, and scientific and medical advisory boards (including any global medical conferences);

1.65.2. all Amgen Sales Force Costs and Partner Sales Force Costs incurred in accordance with the Brand Plan and calculated in accordance with Section 7.2.11 (Calculation of Sales Force Costs);

1.65.3. all training Costs incurred in accordance with Section 5.5 (Training);

1.65.4. all defense, enforcement and cooperation Costs incurred within or materially related to the Collaboration Scope in accordance with Section 10.7 (Defense and Settlement of Third Party Claims), Section 13.4 (Defense of Third Party Claims) and Section 10.8 (Enforcement) ([*]);

1.65.5. all Costs with respect to product liability claims for Products in the Collaboration Scope [*];

1.65.6. all Costs associated with any recalls, returns and withdrawals of a Product in the Collaboration Scope ([*]);

1.65.7. all Costs incurred in connection with Prosecution and Maintenance of Amgen Intellectual Property and Program Intellectual Property in accordance with Section 10.6 (Prosecution and Maintenance) within or materially related to the Collaboration Scope;

1.65.8. all Manufacturing Actual Costs for any samples of Products provided in the Collaboration Scope;

1.65.9. for any commercial supply of Products, all Manufacturing Actual Costs for Products sold;

1.65.10. all manufacturing Costs not otherwise included in Manufacturing Actual Costs, including stability testing and other CMC support costs for such Products, but only to the extent such costs are not included in Development Costs under Section 1.45.3; and

1.65.11. any amounts paid by either Party to Third Parties for rights to manufacture, use or sell a Product in or for the Collaboration Scope to the extent not already included in Manufacturing Actual Costs; *provided*, that [*].

All to the extent incurred after the Effective Date. For clarity, General Costs are exclusive of and do not include Development Costs. Except to the extent already included in overhead, General Costs shall not include either Party's Costs to the extent they solely relate to legal, accounting, finance or alliance management activities associated with overseeing execution of and compliance with this Agreement.

1.66. *"Global Payer Plan"* means the global plan for a Product approved by the JSC that sets forth the strategic direction, positioning, value proposition and reimbursement for such Product.

1.67. *"Governmental Authority"* means any government or supranational administrative agency, commission or other governmental or supranational authority, body or instrumentality, or any federal, state, local, domestic or foreign governmental or supranational regulatory body.

1.68. *"Government Official"* means (i) any Person employed by or acting on behalf of a Governmental Authority; (ii) any political party, party official or candidate; (iii) any Person who holds or performs the duties of an appointment, office or position created by custom or convention; and (iv) any Person who holds himself out to be the authorized intermediary of any of the foregoing.

1.69. *"Housemarks"* means the Amgen Housemarks or the Partner Housemarks, as the case may be.

1.70. *"IFRS"* means the then-current International Financial Reporting Standards, consistently applied.

1.71. *"Indemnified Party"* has the meaning set forth in Section 13.3 (Claim for Indemnification).

1.72. *"Indemnifying Party"* has the meaning set forth in Section 13.3 (Claim for Indemnification).

1.73. *"Indirect Taxes"* means VAT, sales taxes, consumption taxes and other similar taxes.

1.74. *"Infringement Claim"* has the meaning set forth in Section 10.7 (Defense and Settlement of Third Party Claims of Infringement).

1.75. *"Invention"* means any idea, concept, discovery, invention, improvement or trade secret.

1.76. *"Inventorship Margin"* has the meaning set forth in Section 7.2.8.2 (Profit).

1.77. *"Joint Claim"* has the meaning set forth in Section 13.4 (Defense of Third Party Claims).

1.78. *"Joint Product Team"* or *"JPT"* means the individual Product teams established pursuant to Article 2 (Scope and Governance).

1.79. *"Joint Steering Committee"* or *"JSC"* means the steering committee established pursuant to Article 2 (Scope and Governance).

1.80. *"Key Regulatory Filings"* means any (i) Investigational New Drug Application (or similar filing outside the United States); (ii) Biologic Licensing Application (or similar filing outside the United States); (iii) briefing books; and (iv) any other Regulatory Filing designated a Key Regulatory Filing by written agreement of the Parties.

1.81. *"Know-How"* means all tangible and intangible techniques, information, technology, practices, trade secrets, Inventions (whether patentable or not), methods, processes, knowledge, know-how, conclusions, skill, experience, test data and results (including pharmacological, toxicological, manufacturing, and clinical test data and results), regulatory documentation, analytical and quality control data, results or descriptions, software and algorithms, including works of authorship and Copyrights, and materials, including biological materials, compositions and the like. Know-How does not include Patents, Product Trademarks, Amgen Housemarks, Partner Housemarks, or Program Patents and Trademarks.

1.82. *"Losses"* has the meaning set forth in Section 13.1 (Indemnity by Partner).

1.83. *"Manufacturing Actual Costs"* means (i) [*]. Manufacturing Actual Costs will be calculated consistently with other products manufactured by the Manufacturing Lead

and in accordance with GAAP or IFRS, as applicable. For clarity, in the event that the Manufacturing Lead uses a contract manufacturer to perform any manufacturing activities under this Agreement, Manufacturing Actual Costs for such activities will be the price the Manufacturing Lead pays such contract manufacturer for such activities, plus the Costs to manage and to process materials obtained from such contract manufacturer.

1.84. *"Manufacturing Lead"* has the meaning set forth in Section 4.2 (Manufacturing Lead).

1.85. *"Manufacturing Standard Costs"* means, with respect to a Product, [*]. For clarity, (i) where Amgen is the Manufacturing Lead, Amgen's internal clinical standard cost methodology for clinical product [*], and (ii) in the event that the Manufacturing Lead uses a contract manufacturer to perform any manufacturing activities under this Agreement, Manufacturing Standard Cost for such activities will be the price the Manufacturing Lead pays such contract manufacturer for such activities, plus the Costs to manage and to process materials obtained from such contract manufacturer.

1.86. *"Material Anti-Corruption Law Violation"* means a violation of an Anti-Corruption Law relating to the subject matter of this Agreement which would if it were publicly known, in the reasonable view of a Party, have a material adverse effect on it or on its reputation because of its relationship with the other Party.

1.87. *"Medarex Agreement"* means that certain Research and Commercialization Agreement by and among Medarex, Inc., GenPharm International, Inc. and Amgen dated as of December 23, 2002.

1.88. *"[*]"* means Partner's proprietary antibody [*] that is currently in clinical development.

1.89. *"Net Revenues"* means: (i) the aggregate of the gross invoiced sales prices for Products that are sold or transferred for value by either Party or their respective Affiliates to Third Parties in the Collaboration Territory, minus the following amounts incurred or paid (each as recognized by GAAP or IFRS, as applicable, and each to the extent not already deducted when calculating Manufacturing Actual Costs) by such selling Party or its Affiliates with respect to such sales or transfers for value (regardless of the period in which such amounts are incurred or paid):

1.89.1. trade, cash, prompt payment or quantity discounts;

1.89.2. payments to Governmental Authorities, returns, refunds, allowances, rebates and chargebacks;

1.89.3. retroactive price reductions applicable to sales of such Product;

1.89.4. fees paid to distributors, wholesalers, selling agents (excluding any sales representatives of a Party or any of its Affiliates), group purchasing organizations and managed care entities;

1.89.5. the standard inventory cost (actual acquisition or manufacture cost) of devices used for dispensing or administering such Product that are shipped with such Product and included in the gross invoiced sales prices;

1.89.6. credits or allowances for product replacement, whether cash or trade;

1.89.7. any tax, tariff, duty or governmental charge levied on the sales, transfer, transportation or delivery of such Product (including any tax such as a value added or similar tax or government charge), other than franchise or income tax of any kind whatsoever;

1.89.8. [*];

1.89.9. [*]; and

1.89.10. any import or export duties or their equivalent borne by the relevant seller;

plus (ii) any Recoveries made pursuant to Section 10.8 (Enforcement).

1.90. *"Non-Suspending Party"* has the meaning set forth in Section 7.8 (Program Recommitment).

1.91. *"North America"* means the United States and Canada.

1.92. *"[*]"* has the meaning set forth in Section 7.2.8.1.2 (Quarterly Cap).

1.93. *"Operations Budget"* has the meaning set forth in Section 2.4.1.2. The initial Operations Budgets will be agreed in writing by the Parties as soon as reasonably practicable on or after the Effective Date.

1.94. *"Other Detail"* means any Detail other than a First Position Detail or a Second Position Detail.

1.95. *"Out-License Election"* has the meaning set forth in Section 7.8.2.4 (Out-License).

1.96. *"Partner"* has the meaning set forth in the Preamble.

1.97. *"Partner Costs"* has the meaning set forth in Section 7.2.1 (Partner Costs).

1.98. *"Partner Housemarks"* means (i) the corporate logo of Partner, (ii) the trademark "AstraZeneca" and "MedImmune", (iii) any other trademark, trade name or service mark (whether registered or unregistered) containing the word "AstraZeneca" or "MedImmune", and (iv) any other trademark or service mark associated with goods or services of Partner or its Affiliates, but excluding the Product Trademarks and trademarks, trade names or service marks associated with goods or services outside the scope of this Agreement; and all intellectual property rights residing in any of the foregoing.

1.99. *"Partner Indemnitees"* has the meaning set forth in Section 13.2 (Indemnity by Amgen).

1.100. *"Partner Intellectual Property"* means any Know-How, Patents, electronic media registrations (including domain names, usernames, websites, blogs and the like), or Copyright controlled by Partner or its Affiliates that is used (but is not generated or conceived) during the Term by either Party or its Affiliates in the performance of this Agreement. Partner Intellectual Property specifically excludes Program Intellectual Property.

1.101. *"Partner Sales Force Costs"* means the allocable share of Partner's (or its Affiliates') costs for sales representatives that Detail Products in the Collaboration Scope in accordance with this Agreement, calculated in accordance with Section 7.2.11 (Calculation of Sales Force Costs).

1.102. *"Party" or "Parties"* has the meaning set forth in the Preamble.

1.103. *"Party Representatives"* has the meaning set forth in Section 12.3.3.

1.104. *"Patent Coordinator"* means those employees of each of the Parties appointed pursuant to Section 2.10 (Patent Coordinators) to serve as each such Party's primary liaison with the other Party on matters relating to intellectual property as described in this Agreement.

1.105. *"Patent Extensions"* has the meaning set forth in Section 10.9 (Patent Term Extensions).

1.106. *"Patents"* means the issued patents and pending patent applications (including certificates of invention, applications for certificates of invention and priority rights) in any country or region, including all provisional applications, refilings, substitutions, continuations, continuations-in-part, divisions, renewals, all letters patent granted thereon, and all reissues, re-examinations and patent term extensions thereof, and all international or foreign counterparts of any of the foregoing (including supplemental protection certificates, patents of addition and the like).

1.107. *"Person"* means an individual, corporation, partnership, limited liability company, limited partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, "group" as defined in Section 13(d)(3) of the Securities Exchange Act of 1934, as amended, sole proprietorship, unincorporated organization, Governmental Authority or any other form of entity not specifically listed herein.

1.108. *"Phase 1 Trial"* means a clinical trial of a pharmaceutical product that meets the definition of a Phase 1 study for the United States as described in 21 C.F.R. §312.21(a), or its successor regulation, or the equivalent regulation in any other country, including the Phase 1 part of any clinical trial that is a combination Phase 1 Trial and Phase 2 Trial. A *"Phase 1(b) Trial"* means a Phase 1 Trial that is designed to demonstrate evidence of clinical impact.

1.109. *"Phase 2 Trial"* means a clinical trial of a pharmaceutical product that meets the definition of a Phase 2 study for the United States as described in 21 C.F.R. §312.21(b), or its successor regulation, or the equivalent regulation in any other country.

1.110. *"Phase 3 Trial"* means a clinical trial of a pharmaceutical product that meets the definition of a Phase 3 study for the United States as described in 21 C.F.R. §312.21(c), or its successor regulation, or the equivalent regulation in any other country.

1.111. *"Phase 4 Trial"* means any clinical study initiated in the Collaboration Territory for a Product following the first Regulatory Approval for the sale of such Product in the Collaboration Scope for the indication being studied. Phase 4 Trials may include epidemiological studies, modeling and pharmacoeconomic studies, and post-marketing surveillance studies, as well as any clinical study or research study sponsored and conducted by an individual not employed by or on behalf of either Party.

1.112. *"Product"* means any pharmaceutical product containing one of the pharmaceutical compounds listed on the Products Schedule [*].

1.113. *"Product Intellectual Property"* means Amgen Intellectual Property, Partner Intellectual Property, and Program Intellectual Property.

1.114. *"Product Target"* has the meaning set forth on the Distracting Product Schedule.

1.115. *"Product Trademarks"* means any trademark, trade name or service mark (whether registered or unregistered) selected by the JPT for use on, with, or to refer to a Product (other than Amgen Housemarks and Partner Housemarks, as applicable) or used with patient support or other information or services or Promotional Materials associated with a Product in the Collaboration Territory during the Term, and all intellectual property rights residing in the foregoing.

1.116. *"Program Intellectual Property"* means any Know-How, Patents, Product Trademark, trademark application, electronic media registrations (including domain names, usernames, websites, blogs and the like), or Copyright generated or conceived by Amgen, Partner or their respective Affiliates, whether solely or jointly (or together with a Third Party), during the Term as a result of carrying out the Designated Amgen Activities or the Designated Partner Activities, as applicable.

1.117. *"Program Notice"* has the meaning set forth in Section 9.4 (Pre-Clinical Research and Development Programs).

1.118. *"Program Patents and Trademarks"* has the meaning set forth in Section 10.6.3 (Program Intellectual Property).

1.119. *"Promotional Materials"* has the meaning set forth in Section 5.7 (Promotional Materials).

1.120. *"Prosecution and Maintenance"* means the preparation, filing, and prosecution of patent applications and maintenance of patents, as well as re-examinations and reissues with respect to such patents, together with the conduct of interferences, post–grant proceedings (including without limitation post-grant review, inter-partes review, and derivation proceedings in the U.S.) and the defense of oppositions with respect to such patent application or patent; and *"Prosecute and Maintain"* has the correlative meaning.

1.121. *"Quarterly Cap"* has the meaning set forth in Section 7.2.8.1.2 (Quarterly Cap).

1.122. *"Quality Agreement"* means that certain Quality Agreement dated as of the date hereof between the Parties (and substantially in the form attached hereto as the Quality Agreement Schedule) regarding the clinical use of Products manufactured by Amgen, and any subsequent quality agreements between the Parties related to Products supplied pursuant to this Agreement.

1.123. *"Recoveries"* means all monies received by either Party from a Third Party in connection with the final, non-appealable judgment (or judgment with respect to which the time period for appeal has expired), award or settlement of any enforcement with respect to any Product Intellectual Property, to the extent such judgment, award or settlement pertains to activities within the Collaboration Scope.

1.124. *"Re-Entry Notice"* has the meaning set forth in Section 7.8.2.1 (Re-Entry Period).

1.125. *"Re-Entry Period"* has the meaning set forth in Section 7.8.2.1 (Re-Entry Period).

1.126. *"Regulatory Approval"* means an approval for a Product from a Governmental Authority necessary for the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of such Product.

1.127. *"Regulatory Filing"* means any filing with any Governmental Authority with respect to the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of a Product.

1.128. *"Reimbursed Development Costs"* means any Development Costs incurred by either Party for which Amgen is entitled to reimbursement from a Third Party pursuant to the Excluded Territory Agreements; *provided*, that [*] shall not be a Reimbursed Development Cost.

1.129. *"Researching Party"* has the meaning set forth in Section 9.4 (Pre-Clinical Research and Development Programs).

1.130. *"Safety Agreement"* means that certain Safety Agreement to be entered into between the Parties within ninety (90) days of the Effective Date regarding adverse event reporting with respect to Products manufactured by Amgen, and any subsequent safety agreements between the Parties related to Products supplied pursuant to this Agreement.

1.131. *"Second Position Detail"* means a Detail in which the applicable pharmaceutical product is Detailed in the second position (i.e., no more than one (1) other product is presented to or discussed with the healthcare professional before such Product) and/or

the second most predominant portion of time is devoted to the Detailing of such pharmaceutical product.

1.132. *"Segregate"* means, with respect to two (2) programs: (i) to restrict and prevent all program-related contacts and communications between personnel (whether employees, consultants, Third Party contractors or otherwise and whether or not located within the Collaboration Territory (for the purposes of this definition, *"Personnel"*)) working on or involved with the development or commercialization of the first program and Personnel working on or involved with the development or commercialization of the second program; (ii) to ensure that Personnel that are working on the first program will not simultaneously work on the second program and vice versa; (iii) to ensure that confidential information relating to the first program is not shared with or accessed by Personnel that are working on the second program and vice versa; and (iv) from time-to-time, upon the reasonable request of the other Party, to provide information requested relating to the foregoing items (i) through (iii), and to reasonably cooperate to enable the other Party to verify that such restrictions are in place and sufficient to achieve the foregoing. For clarity, [*] as set forth herein.

1.133. *"Specifications"* has the meaning set forth in the applicable Quality Agreement.

1.134. *"Stage 1 Clinical Trial"* means, with respect to each Product, the trial or trials set forth in the Stage 1 Clinical Trial Schedule.

1.135. *"Stage 2 Clinical Trial"* means, with respect to each Product, the trial or trials mutually agreed upon by the Parties at such time either Party provides a Suspension Election with respect to such Product under Section 7.8.1.1 (Suspension Election) (*provided*, that if the Parties are unable to agree upon such trial or trials, then Stage 2 Clinical Trial shall be deemed to be first study in the next phase of development (i.e., the first Phase 3 Trial if the Stage 1 Clinical Trial was a Phase 2b Trial, the first Phase 2b Trial if it were a Phase 2a Trial, the first Phase 2a Trial if it were a Phase 1b Trial, etc.).

1.136. *"Sublicensing Revenue"* means with respect to any Terminated Products, all cash payments (and the fair market value of all non-cash consideration) received by the Continuing Party and/or any of its Affiliates from any Third Party in consideration for a transaction, series of transactions or other arrangement in which such Third Party obtains a license (or sublicense) of the Product Intellectual Property (or any option or other right to obtain a license of the Product Intellectual Property), including, without limitation, up-front payments, milestones, royalties, and research funding (*provided*, that with respect to research funding payments, only the amounts in excess of the Continuing Party's external costs and internal costs directly related to such research activities will be included).

1.137. *"Suspending Party"* has the meaning set forth in Section 7.8 (Program Recommitment).

1.138. *"Suspension Election"* has the meaning set forth in Section 7.8.1.1 (Suspension Election).

1.139. *"Taxes"* means any tax, excise or duty, other than taxes and withholdings upon income.

1.140. *"Technical Feasibility"* means, with respect to any Product manufactured, the first date on which, in the good-faith determination of the Manufacturing Lead, there is a high probability that (i) such related Product candidates will obtain Regulatory Approval for the sale of such Product candidate and (ii) the related costs will be recoverable through the commercialization of such manufactured Product.

1.141. *"Term"* means the period commencing on the Effective Date and continuing in perpetuity, unless and until earlier terminated pursuant to any provision of this Agreement.

1.142. *"Termination Election"* has the meaning set forth in Section 7.8.1.4 (Subsequent Termination).

1.143. *"Third Party"* means any Person that is not a Party, or an Affiliate of a Party.

1.144. *"Third Party Claim"* means any claim, action, lawsuit, or other proceeding brought by any Third Party. Third Party Claim includes any Infringement Claim.

1.145. *"Total Costs"* means all General Costs, Unreimbursed Development Costs and Reimbursed Development Costs.

1.146. *"United States" or "U.S."* means the United States of America and its territories and possessions.

1.147. *"Unreimbursed Development Costs"* means any Development Costs incurred by either Party for which Amgen is not entitled to reimbursement from a Third Party pursuant to the Excluded Territory Agreements; *provided*, that [*] shall be an Unreimbursed Development Cost.

1.148. *"VAT"* means the tax imposed by Council Directive 2006/112/EC of the European Community and any national legislation implementing that directive together with legislation supplemental thereto and in particular, in relation to the United Kingdom, the tax imposed by the Value Added Tax Act of 1994 or other tax of a similar nature imposed in other countries in the Collaboration Territory.

1.149. *"Withholding Party"* has the meaning set forth in Section 8.6.1 (Withholding).

2. SCOPE AND GOVERNANCE

2.1. Purpose of the Collaboration. The purpose of the collaboration is for the Parties to collaborate in the development, manufacture and commercialization of the Products and for the Parties to share in certain costs and revenues related to the Products, all as described in more detail herein.

2.2. Ex-Territory Activities.

2.2.1. *No Rights in Excluded Territory.* The Parties acknowledge that no rights are granted hereunder to Partner with respect to the applicable Product in any country in the Excluded Territory, and that Partner will have no authority with respect to the research, development, manufacture or commercialization of such applicable Products in the Excluded Territory. As between the Parties, Amgen or its licensees will have the sole right to research, develop, manufacture and commercialize such Products in the Excluded Territory. Partner hereby acknowledges that (i) Amgen has previously licensed rights for AMG557 in Japan to Takeda Pharmaceutical Company Limited, and (ii) Amgen obtained its rights for AMG827 under license from Kirin-Amgen, Inc. and its right to develop, manufacture and commercialize AMG827 is subject to certain agreements between Amgen and Kirin-Amgen, Inc.

2.2.2. *License Grant by Partner.* To the extent Amgen is required under any Excluded Territory Agreement to grant rights to a Third Party under any intellectual property rights, Know-How, Regulatory Filings or Regulatory Approvals with respect to a Product in the Excluded Territory, Partner hereby grants Amgen a license (with the right to sublicense) in and to any Partner Intellectual Property, Program Intellectual Property, Know-How, Regulatory Filings or Regulatory Approvals as necessary for Amgen to comply with its obligations under any such Excluded Territory Agreement.

2.2.3. *Kirin-Amgen Royalty Payments.* Additionally, any royalties payable to Kirin-Amgen, Inc. with respect to AMG827 under an Excluded Territory Agreement shall be paid directly by Amgen and shared by the Parties in a manner consistent with Section 7.2.8.2 (Profit).

2.2.4. *Subsequent Rights in Excluded Territory.* If Amgen obtains the right to develop and commercialize Products in all or part of the Excluded Territory, then, upon the request of Partner (made no later than sixty (60) days following receipt of written notice from Amgen regarding such Excluded Territory rights), Amgen and Partner will enter into good faith discussions for the inclusion of such rights under this Agreement on terms to be agreed by Parties (*provided*, that if the Parties are unable to agree upon such terms within [*] of the initiation of such discussions, Amgen shall be free to develop and commercialize Products in such Excluded Territory itself or with a Third Party).

2.2.5. *Prior Consultation.* Amgen will consult with Partner in advance with respect to: (i) [*]; (ii) [*]; and (iii) [*].

2.1. Committees and Teams.

2.3.1. *Formation.* Promptly but not later than sixty (60) days following the Effective Date, the Parties will establish (i) a single, cross-functional Collaboration Review Committee; (ii) a single, cross-functional Joint Steering Committee; and (iii) a cross-functional Joint Product Team for each Product. The JSC and each JPT will each have the right to establish subcommittees or working teams with respect to issues within its area of responsibility as it sees fit (e.g., development, regulatory, pricing, access, manufacturing, commercial or operations), including

local or regional commercialization/operations teams to facilitate the performance of its responsibilities or a finance team to facilitate the implementation of the cost allocations provided in this Agreement.

2.3.2. *Membership.* The CRC will be comprised of three (3) members appointed by each of the Parties or such other number of members as agreed by the Parties (with representatives from each Party for each of development, manufacturing and commercialization). The JSC will be comprised of five (5) members appointed by each of the Parties or such other number of members as agreed by the Parties. The CRC and JSC will each be led by two (2) co-chairs, one (1) appointed by each of the Parties. Each Party will designate such number of members to each JPT as it deems appropriate in order to accomplish the activities for which it is responsible. Each Party will ensure that the CRC, JSC and JPT members appointed by it have (i) the appropriate level of seniority and decision-making authority commensurate with the responsibilities of the committee or team to which they are appointed, and (ii) a range of expertise in the development, manufacture and commercialization of therapeutic products to enable an efficient cross-functional committee or team structure. Each Party will have the right to replace its committee or team members by written notice to the other Party. In the event any committee or team member becomes unwilling or unable to fulfill his or her duties hereunder, the Party that appointed such member will promptly appoint a replacement by written notice to the other Party.

2.3.3. *Meetings.* The CRC will meet semi-annually, via teleconference or videoconference or otherwise (with at least one (1) meeting per calendar year being in person), or as otherwise agreed by the Parties. Additionally, either Party may request a meeting of the CRC to resolve any Critical Matters requiring resolution. The JSC will meet quarterly, via teleconference or videoconference or otherwise (with at least one (1) meeting per calendar year being in person and with at least one (1) meeting per calendar year being scheduled as appropriate to approve [*]), or as otherwise agreed by the Parties. Each JPT and each subcommittee and working team established hereunder will establish a meeting frequency and meeting protocol necessary to coordinate and conduct the activities for which it is responsible, as agreed by the Parties. Any in-person meetings of the CRC or JSC will be held on an alternating basis between Partner's and Amgen's headquarters, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend such meetings as non-voting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Either Party may also call for special meetings of the CRC and JSC as reasonably required to resolve a Critical Matter escalated to the CRC or JSC pursuant to Section 2.4.2 (JPT Deadlocks) or 2.5.2 (JSC Deadlocks) below; *provided*, that the requesting Party provides at least ten (10) business days' prior written notice to the co-chair of such committee appointed by the other Party and such notice includes a proposed agenda for such meeting. All committee and team meetings must have at least two (2) members appointed by each Party in attendance. All committee and team meetings will be conducted in English, and all documents (including Development Plans, Development Budgets, clinical trial protocols for the Products, Operations Budgets, Brand Plans and Commercialization Budgets) will be in English.

2.3.4. *Decision-Making.* Subject to the terms of this Agreement (including Sections 2.4.2 (JPT Deadlocks) and 2.5.2 (JSC Deadlocks) below), the decisions of the

CRC, JSC, JPTs and any subcommittees and working teams established hereunder will be made by consensus of the members thereof, with each Party having one (1) vote.

2.2. Joint Product Teams.

2.4.1. *Responsibilities.* Except for decisions expressly reserved to the JSC or CRC pursuant to Section 2.5 (Joint Steering Committee) or 2.6 (Collaboration Review Committee), respectively, each JPT will (i) establish subcommittees and working teams as necessary to coordinate and conduct its activities hereunder; (ii) coordinate with and oversee the activities of any such subcommittees and working teams; and (iii) be responsible for all operational matters regarding the development, manufacture and commercialization of the Products, including:

2.4.1.1. the following development matters: (i) developing the Development Plan for the applicable Product in the Collaboration Territory and annual updates (or any other updates) thereto; (ii) developing the [*] expense budget for development activities to be undertaken pursuant to the collaboration (the *"Development Budget"*) for such Product in the Collaboration Territory and annual updates (or any other updates) thereto; (iii) preparing all clinical trial protocols for such Product; (iv) providing for communication and discussion between the Parties to optimize the efficacy and safety of the development of such Product in the Collaboration Territory; (v) reviewing and monitoring the activities and progress against the Development Plan, including regulatory matters, site enrollment, patient enrollment, progress of trials, data received and data analysis; (vi) developing observational research and any payer and economic value evidence generation plans for inclusion in the Development Plan; (vii) communicating with the Parties regarding all of the foregoing; and (viii) making such decisions as are specified in Article 3 (Development and Regulatory) to be made by the JPT;

2.4.1.2. the following operations matters: (i) overseeing supply of the applicable Product (in accordance with the applicable Quality Agreement); (ii) reviewing cost of goods of such Product, including yields, success rates and other relevant production statistics; (iii) preparing a draft supply forecast for such Product; (iv) developing the [*] expense budget for manufacturing activities to be undertaken pursuant to the collaboration, including CMC, process development and device-related activities (the *"Operations Budget"*) for such Product in the Collaboration Territory and annual updates (or any other updates) thereto; (v) reviewing other operational issues relating to the manufacture or supply of such Product and any related devices; and (vi) making such decisions as are specified in Article 4 (Manufacturing) to be made by the JPT; and

2.4.1.3. the following commercialization matters: (i) preparing the Brand Plan for the applicable Product and annual updates (or any other updates) thereto; (ii) developing the [*] expense budget for commercialization activities to be undertaken pursuant to the Brand Plans and Country Plans (the *"Commercialization Budget"*) for such Product in the Collaboration Territory and annual updates (or any other updates) thereto; (iii) preparing on an annual basis a three year sales forecast for such Product; (iv) conducting consolidation of expense and sales forecasts from the country or regional level for such Product; (v) reviewing the tactical alignment of commercialization activities with expense budget allocations; (vi) monitoring and reporting on the competitive landscape

for such Product in the Collaboration Territory; (vii) establishing a process for reviewing and approving Promotional Materials and training materials and programs for such Product; (viii) developing a global pricing policy for the applicable Product; and (ix) making such decisions as are specified in Article 5 (Commercialization) to be made by the JPT.

2.4.2. *JPT Deadlocks.* If a JPT is unable to reach consensus on a non-Critical Matter, the decision will be made by the members of such JPT appointed by: (i) the applicable Development Lead, in the case of matters under Section 2.4.1.1; (ii) the applicable Manufacturing Lead, in the case of matters under Section 2.4.1.2; and (iii) the applicable Commercialization Lead, in the case of matters under Section 2.4.1.3. If a JPT is unable to reach consensus on a Critical Matter, the members of such JPT appointed by either Party will have the right to require that such issue be escalated to the JSC for determination; *provided*, that if, in the good faith determination of the Development Lead, the Manufacturing Lead or the Commercialization Lead, as applicable, resolution of such Critical Matter requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on a Product or a Party, the members of such JPT appointed by the Development Lead, the Manufacturing Lead or the Commercialization Lead, as applicable, will have the right to make an interim decision pending JSC determination.

2.3. Joint Steering Committee.

2.5.1. *Responsibilities.* The JSC will (i) oversee the activities of the Parties hereunder generally, each Joint Product Team and any subcommittees or working teams established hereunder, (ii) establish subcommittees and working teams as necessary to coordinate and conduct its activities hereunder, and (iii) be responsible for:

2.5.1.1. the following development matters: (i) approving the Development Plan for each Product in the Collaboration Territory and annual updates thereto; (ii) approving the Development Budget for each Product in the Collaboration Territory and [*] updates thereto; (iii) reviewing and approving all clinical trial protocols for the Products; and (iv) making such decisions as are specified in Article 3 (Development and Regulatory) to be made by the JSC;

2.5.1.2. the following operations matters: (i) approving the Operations Budget for each Product in the Collaboration Territory; (ii) approving the draft supply forecast for each Product; and (iii) making such decisions as are specified in Article 4 (Manufacturing) to be made by the JSC; and

2.5.1.3. the following commercialization matters: (i) approving the Brand Plans and integrating such plans with the Development Plans; (ii) approving a global pricing policy for the applicable Product; (iii) reviewing sales forecasts for each Product; (iv) approving the Commercialization Budget for each Product in the Collaboration Territory; and (v) making such decisions as are specified in Article 5 (Commercialization) to be made by the JSC.

2.5.2. *JSC Deadlocks.* If the JSC is unable to reach consensus on a non-Critical Matter, the decision will be made by the members of the JSC appointed by (i) the applicable Development Lead, in the case of matters under Section 2.5.1.1; (ii) the applicable Manufacturing Lead, in the case of matters under Section 2.5.1.2; and (iii) the applicable Commercialization Lead, in the case of matters under Section 2.5.1.3. If the JSC is unable to reach consensus on a

Critical Matter, the members of the JSC appointed by either Party will have the right to require that such issue be escalated to the CRC for determination; *provided*, that if, in the good faith determination of the Development Lead, the Manufacturing Lead or the Commercialization Lead, as applicable, resolution of such Critical Matter requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on a Product or a Party, the members of the JSC appointed by the Development Lead, the Manufacturing Lead or the Commercialization Lead, as applicable, will have the right to make an interim decision pending CRC determination.

2.4. Collaboration Review Committee. The CRC will be responsible for (i) providing general oversight of the collaboration; (ii) resolving any matters specifically designated to it under this Agreement; and (iii) resolving any Critical Matters escalated to it from the JSC. For clarity, all decisions of the CRC will be made by consensus of the members of the CRC, with each Party having one (1) vote, unless expressly set forth in this Agreement to the contrary.

2.5. Reporting. Each Party will keep the applicable committee or team fully and promptly informed of progress and results of activities for which it is responsible or that it is permitted to conduct hereunder through its members on such committee or team and as otherwise provided herein.

2.6. No Authority to Amend or Modify. Notwithstanding anything herein to the contrary, no committee or team will have any authority to amend, modify or waive compliance with this Agreement.

2.7. Alliance Managers. Promptly after the Effective Date, each Party will appoint a person who will oversee interactions between the Parties between meetings of the committees and teams established hereunder (each, an *"Alliance Manager"*). The Alliance Mangers will have the right to attend all meetings of the CRC, the JSC, the JPTs and any subcommittees and working teams established hereunder, as non-voting participants at such meetings. Each Party may in its sole discretion replace its Alliance Manager at any time by notice in writing to the other Party.

2.8. Patent Coordinators. The Parties will each appoint a Patent Coordinator for each Product promptly after the Effective Date. The Patent Coordinators will serve as the primary contacts and forum for discussion between the Parties with respect to intellectual property matters involving each Product worldwide, and will cooperate with respect to the activities set forth in Article 10 (Intellectual Property). For each Product, the associated Patent Coordinators will discuss a strategy with regard to Prosecution and Maintenance, defense and enforcement of Product Intellectual Property, and defense against allegations that the activities hereunder infringe, or obtaining or amending licenses to, Third Party Patents or Know-How. The Patent Coordinators will meet as often as agreed by them (and at least semi-annually if requested), via teleconference or videoconference or as otherwise agreed, to discuss matters arising out of the activities set forth in Article 10 (Intellectual Property). Each Party may in its sole discretion replace any of its Patent Coordinators at any time by notice in writing to the other Party.

3. DEVELOPMENT AND REGULATORY

3.1. Development Matters.

3.1.1. *Allocation of Development and Regulatory Responsibility.* The JSC will (i) allocate development and regulatory activities to Amgen or Partner on a country-specific or activity-specific basis, taking into consideration all relevant factors (including the strategic objectives and capabilities of each Party) and

(ii) determine whether operational responsibility for any such activity should be transferred from Partner to Amgen or vice versa. Unless and until determined otherwise by the JSC in accordance with the foregoing, the initial allocation of operational responsibility for development and regulatory activities for each Product will be as set forth in the applicable Development Plan.

3.1.2. *Development Lead.* On a Product-by-Product basis, one Party will oversee development and regulatory activities for such Product in the Collaboration Scope (the "*Development Lead*"). The Development Lead for each Product is set forth in the Development/Commercial Lead Schedule. Absent agreement by the JSC to the contrary (as indicated in the applicable Development Plan), it is the expectation of the Parties that the Development Lead will have primary responsibility for day-to-day development activities relating to the relevant Product, including generating protocols, conducting clinical trials, and data collection, verification and analysis. Following the Effective Date, the Parties will promptly meet to coordinate the transition of development and regulatory activities from Amgen to Partner with respect to Products for which Partner is the designated Development Lead in a manner so as to not unduly delay or hamper the development of the relevant Products. The Parties will amend the applicable Development Budgets and Operations Budgets to reflect the reasonable costs to be incurred by each Party in connection with such transfer.

3.1.3. *[*] Updates.* The JSC will review and approve updates to the Development Plans and Development Budgets prior to [*].

3.1.4. *Conduct of Development.* The Parties will cooperate in the conduct of the activities set forth in the applicable Development Plan, including the preparation of protocols and the development of documents therefor. Both Parties will collaborate to achieve globally aligned regulatory documents and interactions for each Product.

3.1.5. *Sharing of Materials.* In the event that it becomes necessary for one Party to provide the other Party with tangible research or biological materials (other than a Product for clinical or commercial use), the Parties will enter into an appropriate material transfer agreement related thereto, which agreement will be subject to this Agreement and will be interpreted consistent with the terms hereof.

3.1.6. *Ownership of Development and Safety Data.* Each Party will solely own all data generated by it or its designee in its development activities conducted hereunder, and such data will be subject to the license from Partner to Amgen under Section 10.5 (License Grant by Partner) or from Amgen to Partner under Section 10.4 (License Grant by Amgen), as applicable. Notwithstanding the foregoing, the Development Lead will own the global safety database, the developmental core safety information (DCSI), and core data sheet for each Product.

3.2. Regulatory Matters.

3.2.1. *Designated Regulatory Party.* Except as set forth in Section 3.2.4 (Manufacturing Matters), the JSC will allocate, on a Product-by-Product and country-specific basis, operational responsibility for regulatory activities to a Party (the "*Designated Regulatory Party*") although there will be a presumption that the Development Lead will also be the Designated Regulatory Party.

3.2.2. *Regulatory Communications and Filings*. The Designated Regulatory Party will prepare, submit and maintain all Regulatory Filings and obtain all Regulatory

Approvals for which it is responsible in accordance with the applicable Development Plan. The other Party will cooperate with the Designated Regulatory Party, at its reasonable request, with respect to any regulatory matters for which the Designated Regulatory Party is responsible. Unless exigent action is required with respect to such Regulatory Filing or material communication, the Designated Regulatory Party will provide the other Party with copies of Key Regulatory Filings prior to submission within a reasonable amount of time (but not less than five (5) business days) to allow such Party to review and comment on such Key Regulatory Filings, and the Designated Regulatory Party will consider all comments and proposed revisions from the other Party in good faith prior to submission (but in the event of a disagreement between the Parties with respect to such comments and proposed revisions, (i) if the Development Lead's determination is consistent with the then-current Development Plan, then the Development Lead's determination shall prevail, and (ii) if the Development Lead's determination is not consistent with the then-current Development Plan, then such matter shall be escalated to the JSC for review (and if a Critical Matter, further escalated to the CRC)). The Designated Regulatory Party will consult with the other Party regarding, and keep the other Party informed of, the status of the preparation of all Regulatory Filings it submits, Governmental Authority review of any such Regulatory Filings, and all Regulatory Approvals that it obtains with respect to a Product. Upon request of the other Party, the Designated Regulatory Party will provide to the other Party copies of all final Regulatory Filings it submits.

3.2.3. *Regulatory Meetings.* The Designated Regulatory Party will consult with the other Party reasonably in advance of the date of any anticipated meeting with a Governmental Authority and will consider any timely recommendations made by the other Party in preparation for such meeting. Upon the request of the other Party, the Designated Regulatory Party will permit the other Party to attend particular meetings between the Designated Regulatory Party and the applicable Governmental Authority. The Designated Regulatory Party will request that the applicable Governmental Authority allow at least one (1) representative of the other Party to attend, solely as an observer, such meetings; *provided*, that the foregoing will not apply to informal meetings or unscheduled teleconferences or meetings or teleconferences otherwise intended by the Governmental Authority to be between it and the Designated Regulatory Party's representatives only. The other Party will strictly follow the Designated Regulatory Party's instructions with respect to any meeting which it attends, and will not discuss the contents of any such meeting with any Governmental Authority except as required by Applicable Law or authorized by the Designated Regulatory Party in writing.

3.2.4. *Manufacturing Matters.* In order to assist the Designated Regulatory Party, the Manufacturing Lead will prepare [*] in English for the relevant Product, and the Designated Regulatory Party will modify as appropriate such module for use in Regulatory Filings in the Collaboration Territory. The Manufacturing Lead will have the option, in order to protect proprietary manufacturing information, to take over operational responsibility from the Designated Regulatory Party for some or all correspondence and for specified official communications, including the preparation and submission of all Regulatory Filings required to be filed with any Governmental Authority in the Collaboration Territory with respect to the manufacture of a Product (except to the extent such transfer of operational responsibility is prohibited by Applicable Law or a Governmental Authority). With respect to any such correspondence and communication, each Party will

promptly provide the other with copies of material written correspondence as reasonably necessary to permit each Party to comply with its relevant regulatory obligations or as otherwise reasonably requested; *provided*, that the Manufacturing Lead will not be required to disclose proprietary or competitively sensitive information unless such disclosure is required by Applicable Law.

3.2.5. *Ownership of Regulatory Filings and Regulatory Approvals.* The Development Lead for a Product will own all right, title and interest in and to any and all Regulatory Filings and Regulatory Approvals directed to such Product and all such Regulatory Filings and Regulatory Approvals will be held in the name of the Development Lead, and the other Party will execute all documents and take all actions as are reasonably requested by the Development Lead to vest such title in the Development Lead, subject to Section 3.1.6 (Ownership of Development and Safety Data) and Section 3.2.4 (Manufacturing Matters). The Development Lead hereby grants to the other Party a non-exclusive, non-transferable (except in connection with a permitted assignment, sublicense or subcontract) "right of reference" (as defined in 21 C.F.R. §314.3(b)) with respect to such Regulatory Filings and Regulatory Approvals solely as necessary for the other Party, if such other Party is the Designated Regulatory Party, to prepare, submit and maintain Regulatory Filings for which it is responsible or as otherwise necessary to perform its obligations hereunder or to comply with Applicable Law.

3.3. Brand Security and Anti-Counterfeiting. The Parties will establish contacts for communication regarding brand security issues and will each reasonably cooperate with the other with respect thereto.

3.4. Product Complaints, Recalls and Returns. The Parties' rights and obligations with respect to nonconformance, recalls and returns of Products will be governed by the applicable Quality Agreement.

3.5. Clinical Trial Register. The Development Lead will, in accordance with Applicable Law and its internal policies, publish the results or summaries of clinical trials relating to a Product on a clinical trial register maintained by it and the protocols of clinical trials relating to such Product on www.ClinicalTrials.gov (or an equivalent register, or as otherwise required by Applicable Law or such Party's policies). The other Party will have the right to publish results or summaries (in the identical form as published by the Development Lead) if the Development Lead has already published in accordance with the foregoing sentence, or the applicable JPT approves such publication. The Parties will cooperate to establish timelines and procedures for JPT review of publications and presentations.

3.6. Sharing of Data and Know-How.

3.6.1. *Generally.* Each Party shall (and shall cause its Affiliates to) reasonably cooperate with the other Party to promptly share and provide access to (i) all clinical trial data and results within the Program Intellectual Property, and (ii) such other Know-How within the Product Intellectual Property as is reasonably necessary for the other Party to exercise its rights or fulfill its obligations under this Agreement. The JSC may establish reasonable policies to effectuate such exchange of data and Know-How between the Parties.

3.6.2. *Manufacturing Know-How.* For clarity, except as provided in Section 3.2.4 (Manufacturing Matters) above, the Manufacturing Lead shall not be obligated

to share with the other Party or provide the other Party access to Know-How related to the manufacture of a Product unless and until such Party becomes the Manufacturing Lead with respect to such aspect of manufacturing of such Product, in which case the Manufacturing Lead shall promptly provide the other Party with access to such manufacturing Know-How within the Product Intellectual Property as is reasonably necessary for such Party to fulfill its obligations as Manufacturing Lead with respect to such Product. All such transfer of manufacturing Know-How shall be overseen and facilitated by the JPT for the applicable Product.

4. MANUFACTURING

4.1. Allocation of Manufacturing Responsibility. Amgen will be responsible for the supply of clinical and commercial product for AMG827. Amgen will be responsible for the initial supply of clinical product for all other Products (the *"Early Stage Programs"*). Amgen will elect at least [*] days prior to the initiation of the first [*] for each Early Stage Program whether or not to continue supplying later stage clinical material and commercial material for such Early Stage Program itself or through a contract manufacturing organization. If Amgen elects not to do so, then Partner will have [*] days to elect to manufacture such later stage clinical material and commercial material for such Early Stage Program (including conducting any process development work related thereto). If neither Party elects to manufacture later stage clinical material and commercial material for such Early Stage Program, then the Parties will mutually agree upon a Third Party manufacturer to conduct process development and clinical and commercial manufacturing. In any event, Amgen will continue to supply clinical material (in the form that exists prior to such election) until such time as Partner or such Third Party manufacturer completes commercial process development and begins to supply such later stage clinical material; *provided*, that, if Partner elects to manufacture later stage clinical material and commercial material, then Partner will promptly and diligently undertake such efforts as are necessary to assume responsibility for such activities.

4.2. Manufacturing Lead. The Party that actually manufactures (itself or through a designee) a specific Product will be the *"Manufacturing Lead"* for such manufactured Product. For clarity, one Party may be the Manufacturing Lead for drug substance and the other Party may be the Manufacturing Lead for drug product. Subject to Section 4.6 (Shortage; Allocation), the Manufacturing Lead will use Commercially Reasonable Efforts to supply Product in a manner sufficient to fulfill demand for the Product in the Collaboration Territory. Additionally, if Partner elects to become the Manufacturing Lead for a Product in accordance with Section 4.1 (Allocation of Manufacturing Responsibility) or is otherwise appointed the Manufacturing Lead by the CRC, the Parties will, with respect to Products manufactured by Partner, negotiate in good faith supplements to the definitions of Manufacturing Standard Costs and Manufacturing Actual Costs in order to make such definitions consistent, on a GAAP or IFRS basis (as applicable), with the manner in which Partner accounts for its other products.

4.3. [*] Updates. The JSC will review and approve updates to the Operations Budgets prior to [*]. Additionally, after Technical Feasibility has been achieved with respect to a Product, on a quarterly basis the Manufacturing Lead will inform the JSC of any expected decrease in [*] that is expected to result in [*]. At the request of the other Party, the Manufacturing Lead will inform the other Party of [*] and will discuss with the other Party [*] with respect thereto. The Manufacturing Lead will have the sole right to determine which of its manufacturing sites will be used to manufacture a Product and may transfer the manufacturing of such Product from one site to another,

so long as such transfer would not reasonably be likely to have a material adverse effect on the continued supply of such Product.

4.4. Distribution. Amgen will be solely responsible for the distribution of Products in the Amgen Distribution Countries. Partner will be solely responsible for the distribution of Products in all other countries in the Collaboration Territory. The Party that actually distributes Products in a particular country will be deemed the *"Distribution Party"* for such country. The Manufacturing Lead of drug product will supply Products for commercial use in labeled, finished form (unless otherwise agreed to by the JSC) to the other Party for distribution in the countries for which the non-Manufacturing Lead for drug product has been allocated distribution responsibility. The non-Manufacturing Lead will reimburse the Manufacturing Lead for such Product at the Manufacturing Lead's Manufacturing Actual Cost upon delivery of such Product to the non-Manufacturing Lead. Such reimbursement will not be included in the calculation of Collaboration Profit (Loss) under Section 7.2 (Profit/Expense Sharing), but rather the non-Manufacturing Lead will be entitled to include such payment as part of Amgen Costs or Partner Costs, as applicable, upon sale of such Product to a Third Party.

4.5. Quality and Safety Agreements. Concurrently with the execution of this Agreement, the Parties have entered into the Quality Agreement with respect to the supply of Products by Amgen to Partner for clinical use. Within ninety (90) days of the Effective Date, the Parties will enter into the Safety Agreement with respect to the supply of Products by Amgen to Partner for clinical use. One year prior to the anticipated first commercial launch of a Product, the Parties will enter into a Quality Agreement with respect to the supply of Products by Amgen to Partner for commercial use and will work in good faith to revise the existing Safety Agreement as necessary. In the event that Partner becomes a Manufacturing Lead for a Product, the Parties will enter into a Quality Agreement with respect thereto and will work in good faith to revise the existing Safety Agreement as necessary.

4.6. Shortage; Allocation. In the event that the Manufacturing Lead reasonably believes that it will not be able to supply requirements for a Product in accordance with a mutually agreed upon supply forecast, the Manufacturing Lead shall provide prompt written notice to the other Party thereof. If the Manufacturing Lead actually cannot supply a Product in accordance with such mutually agreed upon supply requirements, then the Manufacturing Lead will undertake to allocate the manufacturing of Products with its other products so as to not [*]. For clarity, if the Manufacturing Lead cannot actually supply requirements for a Product in accordance with a mutually agreed upon supply forecast, the Manufacturing Lead will reasonably allocate its manufacturing capacity over all its products in the following order of prioritization: (a) to [*]; (b) to [*]; (c) to [*]; and (d) to [*].

5. COMMERCIALIZATION

5.1. Allocation of Commercial Responsibility. The JSC will (i) allocate commercial activities to Amgen or Partner on a Product-by-Product basis and country-specific or activity-specific basis, and (ii) determine whether operational responsibility for any such activity should be transferred from Partner to Amgen or vice versa. Allocations of commercial operational responsibility for countries and regions may be set forth in country plans developed by the applicable JPT that are consistent with the allocation of responsibility established by the JSC and the Brand Plan, taking into account the planned launch timing for the relevant country (as such plans may be updated or modified from time-to-time by the applicable JPT, the *"Country Plans"*). The initial allocation of commercial activities, as well as the guidelines for allocating commercial activities in the future, is as set forth in the Commercial Allocation Schedule.

5.2. Commercial Lead. For each Product, one Party will oversee commercialization activities with respect to all indications for such Product in the Collaboration Scope (the "*Commercial Lead*"). The Commercial Lead for each Product will be as set forth on the Development/Commercial Lead Schedule.

5.3. Initial Plans; [*] Updates. An initial Brand Plan for each Product will be approved by the JSC not later than three (3) months after initiation of the first Phase 3 Trial for such Product; *provided*, that the initial Global Payer Plan and each initial Access and Pricing Plan will be approved by the JSC at such times as the JSC so determines. The JSC will review and approve updates to the Brand Plans and Commercialization Budgets prior to [*].

5.4. All Sales by Distribution Party. Only the Distribution Party with respect to a particular Product in a particular country is authorized to sell such Product in such country. The Distribution Party will have the sole right, in such Party's discretion, to take orders for and returns of, issue credits for, sell, and book sales for, such Product. The non-Distribution Party will promptly forward to the Distribution Party all orders for, and requests to order, such Product. The Distribution Party will have the right to refuse or cancel any order for such Product without liability to the other Party. The non-Distribution Party will not interfere with any agreement of the Distribution Party or any of its Affiliates related to such Product, including contracting for the sale of such Product.

5.5. Training. The JPT will establish a process by which the Parties will review, comment on and approve training materials and programs, and training of the Parties' sales forces for commercialization of the Products will be conducted using only training materials and programs approved in accordance with such process. Each Party will train its respective sales representatives with respect to the promotion of a Product (and update such training from time to time as appropriate) which training will include compliance training as appropriate, all in accordance with the applicable Brand Plan. The Commercial Lead for a Product will own all right, title and interest in the training materials developed hereunder for such Product (except with respect to any Housemarks of the other Party contained therein), and the non-Commercial Lead will execute all documents and take all actions as are reasonably requested by the Commercial Lead to vest title to such training materials in the Commercial Lead.

5.6. Information Concerning Products. Each Party will ensure that no claims or representations in respect of a Product or the characteristics thereof are made by or on behalf of it or its Affiliates (by sales force members or otherwise) that have not been approved by the JPT and neither Party will make any claim or representation that does not represent an accurate summary or explanation of the labeling of such Product.

5.7. Promotional Materials. The JPT will establish a process by which the Parties will review, comment on and approve all written sales, promotion and advertising materials relating to a Product, and other media and materials used to promote the Products or educate the public regarding an indication treated with a Product (collectively and including translations, "*Promotional Materials*"). All Promotional Materials will be produced by the applicable Commercial Lead in accordance with the Brand Plan and such process and any use thereof by the non-Commercial Lead will be subject to prior approval of the Commercial Lead. All Promotional Materials will include, to the extent permitted by Applicable Law, the Amgen Housemarks and the Partner Housemarks. Unless otherwise determined by the applicable JPT, the Commercial Lead will be responsible for the printing and delivery to the other Party of Promotional Materials for use in such other Party's Detailing obligations hereunder. Other than a Party's use and distribution of Promotional Materials that are approved in accordance with the foregoing process and used and distributed in connection with a Party's Detailing of a

Product, neither Party will produce or modify (other than as concepts for consideration by the other Party), or distribute or otherwise use any Promotional Material relating to a Product. If so instructed by the applicable JPT, a Party will immediately cease to use any Promotional Materials and will collect and destroy any such materials from its sales representatives (and record and document such collection and destruction (and provide a copy of such documentation to the other Party upon request)). The Commercial Lead for a Product will own all right, title and interest in and to any and all Promotional Materials for such Product (except with respect to any Housemarks of the other Party included in any Promotional Materials), and the non-Commercial Lead will execute all documents and take all actions as are reasonably requested by the Commercial Lead to vest title to such Promotional Materials in the Commercial Lead.

5.8. Detailing Reports and Audit Rights.

5.8.1. *Reporting*. Each Party will provide the other Party with a report, in such form and manner as determined by the JSC, within forty-five (45) calendar days after the end of each calendar month, setting forth the following information regarding the efforts of the reporting Party's sales force in Detailing each Product during the preceding month: (i) the total number of Details made by such sales force, including a breakdown of First Position Details, Second Position Details and Other Details by target and frequency of Detail by customer priority; and (ii) such other information as may be specified by the JSC. In any country in the Collaboration Territory where the Parties are co-Detailing a Product, each Party will provide the foregoing information with respect to such Product [*]. In any country in the Collaboration Territory where the Parties are not co-Detailing a Product, each Party will provide the foregoing information with respect to such Product [*].

5.8.2. *Audits*. Each Party will keep complete and accurate records of its Detailing of Products in sufficient detail to permit the other Party to audit its performance of Details hereunder. During regular business hours, with not less than ten (10) business days' advance written notice and under reasonable obligations of confidentiality, a Party will permit the other Party or its authorized representatives to: (i) have access to the records of Detailing activities maintained by such Party for purposes of verifying the accuracy of reports described in Section 5.8.1 (Reporting); and (ii) audit such records; *provided*, that such audits may not be performed by a Party more than once per calendar year, such records will be open (in such form as may be available or reasonably requested) to inspection for at least three (3) years following the end of the period to which they pertain, and such records for any particular calendar year will only be subject to one (1) audit. Any and all audits undertaken pursuant to this Section 5.8.2 (Audits) will be performed at the sole and exclusive expense of the auditing Party and will not be included in Amgen Costs or Partner Costs, as the case may be, for purposes of calculating Collaboration Profit (Loss). If an audit reveals an overstatement of Details of greater than [*] of the correct amount for the audited period, then the audited Party will pay the reasonable out-of-pocket cost of such inspection.

5.9. Competing Products. If either Party or its Affiliates has sales representatives Detailing both a Product and a non-Product that is approved by a Governmental Authority for use in the same indication as such Product (a "*Competing Product*"), then, in addition to the reporting obligations contained in Section 5.8.1 (Reporting), such Party will provide to specified employees of the other Party (as specified by such Party's JSC members) with a report within thirty (30) calendar days after the end of each calendar month, setting forth [*]. The purpose of such report shall be solely to substantiate the calculation of Sales Force Costs. It shall only be used by the specified employees and it

shall not be used by either Party in violation of any Applicable Law. If the JSC or CRC authorizes a sales representative to Detail a Product in the First Position Detail, then [*].

5.10. Sales Force [*]. On a country-by-country and Product-by-Product basis, during the period of time beginning [*] of such Product in such country, if either Party intends to [*] in such country that are expected to [*] such Product, then such Party shall provide the other Party with at least sixty (60) days' prior written notice. In such event, at the request of either Party, the JSC shall meet to [*] in such country (with escalation to the CRC if the JSC is unable to agree on such [*]). The Party that has [*] during the applicable period (but not to exceed [*] that are in excess of its [*].

6. PERFORMANCE STANDARDS

6.1. Collaborative Activities. Activities to be undertaken by the Parties hereunder will be conducted in a collaborative manner as determined by the committee or team overseeing such activities, and in accordance with the terms and conditions of this Agreement, as applicable.

6.2. Diligence and Performance Standards. Subject to the decisions made by and oversight of the committees and teams established hereunder, each Party will use, and will assure that each of its Affiliates uses, Commercially Reasonable Efforts in the performance of its and their activities hereunder. Each Party will conduct, and ensure that each of its Affiliates conducts, all of its and their activities with respect to the development, registration, manufacture, distribution, promotion and commercialization of a Product in accordance with this Agreement, the applicable Development Plan, the applicable Brand Plan, applicable Global Payer Plan, applicable Access and Pricing Plan, applicable Country Plans, accepted national and international pharmaceutical industry codes of practices in and for the Collaboration Territory (including the Pharmaceutical Research and Manufacturers of America (PhRMA) Code of Pharmaceutical Marketing Practices and the American Medical Association (AMA) Guidelines on Gifts to Physicians from Industry, as the same may be amended from time to time), and all Applicable Law. The Parties will provide each other with all reasonably requested cooperation to enable each of them to comply with Applicable Law and accepted national and international pharmaceutical industry standards, including permitting each Party to verify the other Party's compliance therewith.

6.3. Violation of Laws. Each Party will promptly notify the other Party of any violation of Applicable Law by its personnel with respect to the conduct of activities under this Agreement. In the event of any such violation, the Parties will promptly confer regarding any such violation and will promptly take remedial or preventative action as may be reasonably required by the applicable JPT with respect thereto. The Parties will have the right to require that any personnel that materially violates Applicable Law or applicable national or international pharmaceutical industry codes of practices cease to perform activities under this Agreement.

6.4. Use of Affiliates and Third Party Contractors. Each Party will perform the activities designated to it itself or through any of its Affiliates, and any proposed use of a Third Party to conduct such activities will be subject to the other Party's prior written consent, such consent not to be unreasonably withheld; *provided*, that (i) Partner's consent will not be required for activities Amgen has, prior to the Effective Date, arranged to have performed by Third Parties and which have been disclosed to Partner prior to the Effective Date, and (ii) either Party will be permitted to, upon thirty (30) days' prior written notice to the other Party, engage a Third Party contract manufacturer, contract research organization, contract sales organization, distributor or wholesaler without the other Party's consent. Cost overruns resulting from either

Party's use of a Third Party to conduct any such activities will be subject to Section 7.2.6 (Overruns). Each Party will be responsible for compliance by its respective Affiliates and Third Party contractors with this Agreement and will be responsible for all acts and omissions of such Affiliates and Third Party contractors as if committed or omitted by the applicable Party.

6.5. Management of Personnel. Each Party will have sole authority and responsibility for recruiting, hiring, managing, compensating (including paying for all benefits, wages, special incentives, workers' compensation and employment taxes), disciplining, firing and otherwise controlling the personnel provided by such Party for performance of its obligations hereunder; *provided*, that each Party will require its personnel to be subject to a confidentiality agreement and Invention assignment commitment prior to, and as a condition of, such personnel performing any such activities hereunder. Each Party will provide the day-to-day management of its sales representatives and other personnel, including furnishing administrative support, financial resources, equipment and supplies.

7. UP-FRONT PAYMENT AND PROFIT/EXPENSE SHARING

7.1. Up-front Payment. As partial consideration for the rights granted to Partner by Amgen pursuant to the terms of this Agreement, Partner will pay to Amgen a non-refundable, non-creditable payment equal to Fifty Million Dollars ($50,000,000.00) within fifteen (15) days after the Effective Date, payable by wire transfer of immediately available funds in accordance with wire transfer instructions of Amgen that will be provided in writing to Partner prior to the Effective Date.

7.2. Profit/Expense Sharing. The Parties will share in profits and losses generated by Products in the Collaboration Scope as follows:

7.2.1. *Partner Costs*. Within forty-five (45) days after the end of each calendar quarter Partner will provide to Amgen a detailed, itemized report of its Development Costs and General Costs, on a Product-by-Product basis, incurred by Partner or its Affiliates in accordance with this Agreement (collectively, *"Partner Costs"*) in such quarter in the format set forth in the Invoice Schedule attached hereto. In addition to the annual JSC approval of the relevant budgets for each Product, prior to the end of each calendar year, Partner will provide Amgen with a non-binding estimate of its Development Costs and General Costs for each Product for the [*] period (detailed on a calendar year basis) following the [*] covered by such approved budget; *provided*, that the Parties will review and discuss such estimated costs at the JSC.

7.2.2. *Amgen Costs*. Within forty-five (45) days after the end of each calendar quarter Amgen will provide to Partner a detailed, itemized report of its Development Costs and General Costs, on a Product-by-Product basis, incurred by Amgen or its Affiliates in accordance with this Agreement (collectively, *"Amgen Costs"*) in such quarter in the format set forth in the Invoice Schedule attached hereto. In addition to the annual JSC approval of the relevant budgets for each Product, prior to the end of each calendar year, Amgen will provide Partner with a non-binding estimate of its Development Costs and General Costs for each Product for the [*] period (detailed on a calendar year basis) following the [*] covered by such approved budget; *provided*, that the Parties will review and discuss such estimated costs at the JSC. For clarity, any costs incurred by or on behalf of Amgen in connection with the research and development of AMG557 for the sole benefit of Japan or the research and development of AMG827 for the sole benefit of the applicable Excluded Territory will not be included in Amgen Costs.

7.2.3. *FTE Rate*. The FTE Rate used for calculation of Costs pursuant to this Article 7 (Profit/Expense Sharing) with respect to any activity will be the relevant FTE Rate for the calendar year in which such activity was undertaken.

7.2.4. *Income Taxes*. For the avoidance of doubt, income and withholding taxes imposed on either of the Parties hereunder will not be included in cost sharing hereunder.

7.2.5. *Exchange Rate*. For purposes of calculating quarterly balancing payments as set forth in Section 7.2.9 (True-Up), Net Revenues, Amgen Costs and Partner Costs will be converted from local currency (if different from U.S. Dollars) to U.S. Dollars in accordance with Section 8.3.2 (Conversions).

7.2.6. *Overruns*. Each Party will promptly notify the other Party upon becoming aware that the anticipated Costs to be incurred by such Party for a given calendar year will be in excess of the applicable Development Budget, Operations Budget or Commercialization Budget. Unless otherwise agreed by the Parties in advance, in writing, Costs reported by a Party pursuant to Section 7.2.1 (Partner Costs) or 7.2.2 (Amgen Costs) incurred with respect to a Product in excess of [*] percent ([*]%) of the aggregate amounts budgeted to be incurred by or on behalf of such Party for its activities for such Product in such calendar year in the then-current applicable Development Budget, Operations Budget or Commercialization Budget, respectively, will not be included in the calculation of profit (or loss) pursuant to Section 7.2.8 (Calculation of Profit (or Loss)); *provided*, that such Partner Costs and Amgen Costs in excess of such amount will be included in the calculation of profit (or loss) pursuant to Section 7.2.8 (Calculation of Profit (or Loss)) (A) to the extent such Costs were attributable to: (i) a change in Applicable Law; (ii) a Force Majeure event; [*].

7.2.7. *Net Revenues*. Within five (5) business days prior to the end of each calendar quarter, each Party will provide the other Party with a reasonably detailed estimate of Net Revenues for such calendar quarter in the countries for which it is the Distribution Party. Within thirty (30) days after the end of each calendar quarter, each Party will provide the other Party with a report of Net Revenues for such calendar quarter in the countries for which it is the Distribution Party, which report will contain a detailed and itemized calculation of Net Revenues for each Product in such countries during such calendar quarter.

7.2.8. *Calculation of Profit (or Loss)*.

7.2.8.1.**Costs.**

7.2.8.1.1. **Allocation.** On a calendar quarter-by-calendar quarter basis, Partner will be responsible for one hundred percent (100%) of the following cost items, in the order set forth below, up to the Quarterly Cap for such calendar quarter. Thereafter, Amgen shall be responsible for one hundred percent (100%) of such costs for such calendar quarter.

7.2.8.1.1.1.**Unreimbursed Development Costs and General Costs.** First, Partner will be responsible for one hundred percent (100%) of Unreimbursed Development Costs and General Costs up to the Quarterly Cap.

7.2.8.1.1.2.**Reimbursed Development Costs.** If, following reimbursement for Unreimbursed Development Costs and General Costs, the Quarterly Cap has not yet been met, then Partner will be responsible for one hundred percent (100%) of Reimbursed Development Costs up to the Quarterly Cap.

7.2.8.1.2. **Quarterly Cap.** The *"Quarterly Cap"* for a given calendar quarter shall, during the applicable calendar year set forth below, be as follows:

Calendar Year	Quarterly Cap
2012	65% of Total Costs for the applicable calendar quarter - [*]
2013	65% of Total Costs for the applicable calendar quarter + [*]
2014	65% of Total Costs for the applicable calendar quarter
2015 and each year thereafter	50% of Total Costs for the applicable calendar quarter

The Development Costs and General Costs for any calendar quarter will only include [*] of Development Costs and General Costs incurred in the conduct of the [*] set forth in the Development Plan for [*]. In the event either (i) the designated endpoints set forth on the [*] Designated Endpoints [*] Schedule for the [*] are met, or (ii) the Parties agree to initiate a [*], then Amgen shall have the right to allocate an amount equal to [*] of the Development Costs and General Costs incurred after the Effective Date in the conduct of the [*] between: (a) a one-time success milestone payment from Partner to Amgen (payable within forty-five (45) days of notice from Amgen of the allocation between (a) and (b) provided below) and (b) an immediate increase (applied evenly) to the Quarterly Cap for the subsequent four (4) calendar quarters. Amgen shall notify Partner in writing as to the allocation, which must total one hundred percent (100%) between (a) and (b). Additionally as of the Effective Date, the Parties agree that the [*] set forth in the Development Plan for [*] is optional for the [*]. The Parties will evaluate whether or not it is beneficial to conduct the [*] as part of such trial. If the Parties disagree, then Amgen shall have the right, [*], to conduct the [*].) If the [*] meets the designated endpoints set forth on the [*], then Partner will reimburse Amgen [*] of the Costs associated with the [*] (to be allocated between a milestone or increase to the Quarterly Cap as set forth in the forgoing sentence at Amgen's option) and any Costs associated with the [*] incurred after such endpoints have been met will be included in Amgen Costs and shared in accordance with Section 7.2.8.1 (Costs).

1.1.1.1.**Profit.** The total profit for a calendar quarter will be calculated by Amgen by first deducting from aggregate Net Revenues for each Product for such quarter a percentage of such Net Revenues equal to the applicable "Inventorship Margin" set forth below, which will be paid to Amgen to reflect Amgen's inventorship of the Products:

Inventorship Margin	
AMG827	Other Products
[*]	[*]

Additionally, [*]. After deduction of the Inventorship Margin [*], the remaining Net Revenues will be shared by the Parties equally.

7.2.9. *True-up*. Within sixty (60) days after the end of each calendar quarter, Amgen will calculate and provide to Partner a report of the amount each Party is responsible for under Section 7.2.8.1 (Costs) for such quarter, and a report of the amount each Party is entitled to under Section 7.2.8.2 (Profit). The resulting amounts under Sections 7.2.8.1 (Costs) and 7.2.8.2 (Profit) will be the *"Collaboration Profit (Loss)"* for such calendar quarter. A balancing payment will be made between the Parties in order to effect the profit and loss sharing allocation set forth in Section 7.2.8 (Calculation of Profit (or Loss)). The net paying Party will make a payment pursuant to this Section 7.2.9 (True-up) within thirty (30) days after delivery of such report of Collaboration Profit (Loss).

7.2.10. *Payments.* Payments pursuant to this Article 7 (Profit/Expense Sharing) will be made in accordance with the provisions of Article 8 (Payments).

7.2.11. *Calculation of Sales Force Costs*. Sales force FTE costs for each of the Parties will be determined by including in Partner Costs or Amgen Costs, as the case may be, a pro rata portion of each Party's sales representative's FTE Rate as follows: (i) [*] if such sales representative Details only a single Product (and no other products) with the approval of the CRC; (ii) [*] if such sales representative Details two (2) products with a Product as the First Position Detail or Details only a Product without the approval of the CRC; (iii) [*] if such sales representative Details three (3) or more products with a Product as the First Position Detail; (iv) [*] if such sales representative Details two (2) products with a Product as the Second Position Detail; (v) [*] if such sales representative Details three (3) or more products with a Product as the Second Position Detail; and (vi) [*] if such sales representative Details three (3) or more products with a Product as the Other Detail. If a sales representative Details more than one (1) Product, then the foregoing percentages will be aggregated for each such Product. For the avoidance of doubt, if a sales representative Details a Product in more than one (1) position, then a pro rata share of the foregoing percentages, to be calculated based on the time spent by such sales representative on Detailing such Product in each such position, will be included in Partner Costs or Amgen Costs, as the case may be. For periods in which sales representatives are performing activities in support of the collaboration but are not Detailing Products (e.g., during launch preparation or training), FTE costs will be calculated based upon percent of effort, resource utilization or other reasonable measure, in each case calculated and allocated in accordance with the applicable Party's accounting procedures, consistently applied.

7.2.12. *Kirin-Amgen and Takeda Payments*. For clarity, the Parties agree and acknowledge that any payments received by Amgen from (i) in the case of

AMG827, Kirin-Amgen, Inc. or Kyowa Hakko Kirin Co., Ltd and (ii) in the case of AMG557, Takeda Pharmaceutical Company Limited, in each case pursuant to the related Excluded Territory Agreement with such Third Party, shall be excluded from the calculation of Collaboration Profit (Loss). Any such payments shall not, in any way (in part or in full), reduce Amgen Costs hereunder, and Amgen shall be entitled to retain any such payments in full without compensation to, or any separate accounting or audit right undertaken by, Partner.

7.3. Example. The Profit (Loss) Example Schedule sets forth an example of calculation and true-up of the Collaboration Profit (Loss).

7.4. Calculation of Net Revenues. In calculating Net Revenues for the purposes of this Article 7 (Profit/Expense Sharing):

7.4.1. *Free Products.* Any disposal of a Product at no charge for, or use of a Product without charge in, clinical or pre-clinical trials, given as free samples, or distributed at no charge to patients unable to purchase the same will not be included in Net Revenues.

7.4.2. *Bundled Products.* Where a Product is sold in a Bundle, then for the purposes of calculating Net Revenues under this Agreement, such Product will be deemed to be sold for an amount equal to $[X \div (X + Y)] \times Z$, where: X is the average sales price during the applicable reporting period generally achieved for such dosage form of such Product in the Collaboration Scope; Y is the sum of the average sales price during the applicable reporting period generally achieved in the Collaboration Territory, when sold alone, by each pharmaceutical product in the relevant dosage form included in the Bundle (excluding such Product); and Z equals the price at which the Bundle was actually sold. In the event that such Product or one or more of the other pharmaceutical products in the Bundle are not sold separately in the relevant dosage form, Net Revenues from the sale of such Bundle will be reasonably allocated between such Product and the other product(s) in such Bundle based upon their relative values and the Parties will determine the equitable fair market prices to apply to such Bundle; *provided*, that in the event of a disagreement with respect to such relative values, the Parties will engage a mutually agreed upon independent expert to make the final determination with respect thereto. Notwithstanding the foregoing, no Product will be sold in a Bundle if such sale would violate Applicable Law.

7.5. Excluded Losses. The following losses will not be charged to the Collaboration Profit (Loss): (i) losses of a Party to the extent attributable to a breach of this Agreement by such Party, or (ii) losses subject to indemnification pursuant to Section 13.1 (Indemnity by Partner) or Section 13.2 (Indemnity by Amgen).

7.6. Manufacturing Costs Calculation and True-Up. Manufacturing Standard Costs for a Product, calculated as part of Development Costs, will be included in Amgen Costs and Partner Costs, as applicable, at the time of manufacture of such Product. Prior to Technical Feasibility, Manufacturing Actual Costs for a Product intended for use in a clinical trial, calculated as part of Development Costs, will be included in Amgen Costs and Partner Costs, as applicable, at the time of manufacture of such Product. After Technical Feasibility, Manufacturing Actual Costs for a Product intended for use in a clinical trial, calculated as part of Development Costs, will be included in Amgen Costs and Partner Costs, as applicable, at the time such Product is shipped to a site for use of such Product in a clinical trial. Subject to Section 4.4 (Distribution), Manufacturing Actual Costs for a Product for commercial use, calculated as part of General Costs, will be included in Amgen Costs and Partner Costs, as applicable, at the time of sale of such

Product. In addition, due to the fact that Manufacturing Actual Costs may not be known at the time such costs are to be included within the Collaboration Profit (Loss), for the purposes of determining Development Costs or General Costs for a particular calendar quarter, the Manufacturing Lead will, to the extent any manufacturing costs are to be calculated using Manufacturing Actual Costs, use the then-current estimated Manufacturing Actual Costs for such calendar quarter. By March 31 of each calendar year, the Manufacturing Lead will reconcile the estimated Manufacturing Actual Costs included in Development Costs and General Costs in the prior calendar year with the final Manufacturing Actual Costs for such Product and provide such reconciliation to the other Party. If such reconciliation leads to an over or under payment by either Party, a balancing payment will be made between the Parties in order to maintain the intended profit and loss sharing allocation set forth in this Agreement within thirty (30) days after delivery of such reconciliation report by the Manufacturing Lead and agreement thereon by the Parties.

7.7. Budget Deadlocks. In the event that the JSC is unable to approve [*] Development Budget, Operations Budget or Commercialization Budget prior to the expiration of any such budget, then, until approval of such budget by the CRC, each Party will be entitled to continue the Designated Amgen Activities and Designated Partner Activities, as applicable, and include its Development Costs and General Costs, as applicable, in the calculation of Collaboration Profit (Loss) for any calendar quarter not covered by an approved budget, until such time as the aggregate Development Costs and General Costs of such Party included in the calculation of Collaboration Profit (Loss) for [*] equal the amount of such Party's Development Costs and General Costs included in the then most recent estimate provided under Sections 7.2.1 (Partner Costs) and 7.2.2 (Amgen Costs), as applicable, plus [*] of such estimate.

7.8. Program Recommitment. [*], after the applicable Continued Development Meeting for a Product has been held and upon consultation at the CRC, in the event either (or both) Party(ies) do not wish to continue to participate in the continued development and commercialization of such Product, each Party will have the right to suspend its participation by providing the other Party with a written notice thereof on or prior to [*] days following the applicable Continued Development Meeting. A Party so suspending its commitment will be referred to as a *"Suspending Party"* and a Party not doing so a *"Non-Suspending Party"*.

7.8.1. *Suspension.*

7.8.1.1. *Suspension Election.* If only one Party delivers a notice of suspension with respect to a Product (a *"Suspension Election"*), then the remaining provisions of this Section 7.8 (Program Recommitment) shall apply. If both Parties deliver a notice of suspension with respect to a Product, then the Agreement shall be deemed to be terminated with respect to such Product in accordance with Section 14.2 (Termination for Convenience) and Section 14.6.1 (Product by Product Termination) and Amgen shall be the Continuing Party with respect to such Product.

7.8.1.2. *Transition.* Upon making a Suspension Election, the Suspending Party will, at the Non-Suspending Party's cost, undertake all reasonable efforts to effect a smooth and orderly transition of its development, regulatory and commercial activities and responsibilities under this Agreement with respect to such Product to the Non-Suspending Party. If the Suspending Party is the Manufacturing Lead for such Product, then, at the Non-Suspending Party's cost, the Suspending Party will use all reasonable efforts to continue to supply Product for clinical use and complete any commercial process development activities initiated prior to the effective

date of such Suspension Election; *provided*, that, the Manufacturing Lead will have the right to transition such manufacturing to a contract manufacturer or, if agreed to by the Non-Suspending Party, to the Non-Suspending Party. For clarity, from and after the effective date of any Suspension Notice, the Suspending Party shall not be liable for any Development Costs or General Costs for such Product committed before the effective date of the Suspension Notice but not yet incurred at that date or otherwise incurred after such date.

7.8.1.3. *Committee Participation.* Upon making a Suspension Election and until such time as the Suspending Party elects to resume funding its share of Development Costs and General Costs with respect to such Product pursuant to Section 7.8.2 (Re-Entry Right) below, the Suspending Party's right to participate on the CRC, the JSC, any JPT and any subcommittee or subteam thereunder will be limited to a right to participate in any meetings brought before such committee or team without any right to vote on any matter that specifically relates to such Product (for clarity the Suspending Party will retain the right to vote on any matter that relates to any other Product). Additionally, if the Suspending Party was the Development Lead and Commercial Lead for such Product, then the Non-Suspending Party shall be the Development Lead and Commercial Lead going forth, and the Suspending Party shall not be entitled to resume such role even if such Party elects to resume funding its share of Development Costs and General Costs with respect to such Product pursuant to Section 7.8.2 (Re-Entry Right) below. Additionally, the Non-Suspending Party shall promptly share with, and provide access to, the Suspending Party (i) all clinical trial data and results within the Program Intellectual Property, (ii) such other Know-How within the Product Intellectual Property generated before the date of the Suspension Election; and (iii) any other information reasonably requested by the Suspending Party related to such Product.

7.8.1.4. *Subsequent Termination.* If the Non-Suspending Party subsequently decides that it is no longer willing to continue further development and commercialization of the Product, then the Non-Suspending Party may elect to terminate further development and commercialization by providing the Suspending Party with [*] prior written notice (a *"Termination Election"*). If the Suspending Party is Partner and Amgen delivers a Termination Election during the Re-Entry Period, then upon receipt of such Termination Election from Amgen, Partner shall have the right upon prior written notice, delivered by no later than [*] following receipt of Amgen's Termination Election, to elect to continue with the further development and commercialization of the Product, in which case, Partner shall thereafter be deemed to be the Non-Suspending Party and Amgen shall be deemed to be the Suspending Party. If Partner does not elect within such [*] period to continue with such development or commercialization or if Partner is the Non-Suspending Party, then upon the effective date of a Termination Election, the Agreement shall be deemed to be terminated with respect to such Product in accordance with Section 14.2 (Termination for Convenience) and Section 14.6.1 (Product by Product Termination) and Amgen shall be the Continuing Party with respect to such Product.

7.8.2. *Re-Entry Rights.*

7.8.2.1.*Re-Entry Period.* With respect to any non-terminated Product subject to a Suspension Election, at any time beginning upon receipt of the Suspension Election until [*] following the receipt of the flash memo for the applicable Stage 2 Clinical Trial for such Product and receipt of any information requested by the Suspending Party that is reasonably necessary to determine whether to re-enter the program (the *"Re-Entry Period"*), the Suspending Party will have the right to re-enter the program by written notice (a *"Re-Entry Notice"*) to the Non-Suspending Party, effective as of the date of receipt of such notice by the Non-Suspending Party.

7.8.2.2.*Re-Entry Payment.* In the event of such re-entry, the Suspending Party will pay the Non-Suspending Party an amount equal to [*].

7.8.2.3.*Lapse.* If the Suspending Party fails to provide the Re-Entry Notice with respect to a Product during the applicable Re-Entry Period, then the Suspending Party shall be deemed to have terminated the Agreement with respect to such Product in accordance with Section 14.2 (Termination for Convenience) and Section 14.6.1 (Product by Product Termination).

7.8.2.4.Out-license. If, during the Re-Entry Period for a Product, the Non-Suspending Party elects to grant to a bona fide Third Party the exclusive right to develop or commercialize such Product in any country within the Collaboration Territory, then the Non-Suspending Party will provide the Suspending Party with [*] prior written notice (the *"Out-License Election"*). If the Suspending Party fails to provide a Re-Entry Notice within [*] of receipt of the Out-License Election and the Out-License Election relates to only certain countries within the Collaboration Territory, then the Suspending Party's right to re-enter the program shall exclude such countries. If the Suspending Party fails to provide a Re-Entry Notice within [*] of receipt of the Out-License Election and the Out-License Election relates to all countries within the Collaboration Territory, then, then the Suspending Party's right to provide a Re-Entry Notice with respect to such Product shall terminate.

8. PAYMENTS

8.1. Appropriate Measure of Value. Each of the Parties acknowledges that the value provided by the other hereunder is comprised of many related items, including performance of various services, access to development, regulatory, manufacturing and commercial expertise, clinical data and other financial and non-financial consideration and that the amount of the Inventorship Margin, and the ratio of profit and expense sharing set forth herein are intended to capture such value as an aggregate. Therefore, the increase, decrease or lapse of any particular items or rights (including Patents), including allocation of operational responsibilities between the Parties, will not affect the amount of such payment, or the ratio of profit and expense sharing and the Parties agree that both the amount and duration of such payment and the ratio of profit and expense sharing are reasonable.

8.2. No Other Compensation. Other than as explicitly set forth in this Agreement, neither Party will be obligated to pay any additional fees, milestone payments, royalties or other payments of any kind to the other hereunder.

8.3. Currency.

8.3.1. *Payments.* All payments made hereunder between the Parties will be made in U.S. Dollars except as set forth in Section 8.5 (Blocked Currency) or as otherwise agreed by the Parties. Each Party will pay all sums due hereunder by wire transfer, or electronic funds transfer (EFT) in immediately available funds. If the EFT option is chosen by Amgen or Partner, a completed electronic funds transfer form will be provided in a timeframe that facilitates timely payment. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments. All amounts set forth in any budget established under this Agreement will be expressed in U.S. Dollars except as otherwise agreed by the Parties.

8.3.2. *Conversions.* With respect to amounts required to be converted into another currency for calculation or payment, hereunder, such amounts will be converted using a rate of exchange which corresponds to the rate used for conversion between the relative currencies by whichever Party recorded the relevant receipt or expenditure, for the respective reporting period in its books and records that are maintained in accordance with GAAP or IFRS, as the case may be. If a Party is not required to perform such a currency conversion for its GAAP or IFRS reporting with respect to the applicable period, then for such period such Party will make such conversion using the rate of exchange which corresponds to the noon buying rate as published in the Wall Street Journal, Eastern U.S. Edition on the second to last business day of the calendar quarter (or such other publication as agreed-upon by the Parties) in which such receipt or expenditure was incurred.

8.4. Audits. Each Party will keep complete and accurate records pertaining to the activities to be conducted hereunder in sufficient detail to permit the other Party (the *"Auditing Party"*) to confirm the accuracy of all payments due hereunder, and such records will be open (in such form as may be available or reasonably requested) to inspection for [*] following the end of the period to which they pertain. The Auditing Party will have the right, at its own expense to have an independent, certified public accountant, selected by it, perform a review of the records of the other Party (the *"Audited Party"*) applicable to amounts payable hereunder (including any records kept in the ordinary course of the Audited Party's business) during regular business hours, with not less than ten (10) business days' advance written notice and under reasonable obligations of confidentiality. The report of such accountant will be made available to both Parties simultaneously, promptly upon its completion. The Auditing Party's right to perform an audit pertaining to any calendar year will expire [*] after the end of such year and the books and records for any particular calendar year will only be subject to one (1) audit. Should an inspection pursuant to this Section 8.4 (Audits) lead to the discovery of a payment discrepancy, then the appropriate Party will pay to the other the amount of the discrepancy (plus, if the error was in favor of the Auditing Party, interest accrued at the Contract Interest Rate, compounded annually from the day the relevant payment(s) were due). If a payment discrepancy was greater than [*] of the correct amount for the audited period and the discrepancy was in favor of the Audited Party, then the Audited Party will pay the reasonable out-of-pocket cost of such inspection, but in no case will the costs of an audit pursuant to this Section 8.4 (Audits) be included in Partner Costs or Amgen Costs or otherwise included in the calculation of Collaboration Profit (Loss). This Section 8.4 (Audits) does not apply to or include manufacturing audits or regulatory inspections.

8.5. Blocked Currency. If Applicable Law in the Collaboration Territory prevents the prompt remittance of any payments with respect to sales therein, the paying Party will have the right and option to make such payments by depositing the amount thereof in local currency to the other Party's account in a bank or depository in such country.

8.6. Taxes.

8.6.1. *Withholding*. If Applicable Law requires a Party to pay or withhold Taxes with respect to any payment to be made pursuant to this Agreement, the paying Party will notify the other in writing of such payment or withholding requirements prior to making the payment and provide such assistance to the receiving Party, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in such Party's efforts to claim an exemption from or reduction of such Taxes. Each Party will withhold any Taxes required by law to be withheld from the amount due, remit such Taxes to the appropriate tax authority, and furnish the other Party with proof of payment of such Taxes promptly following payment thereof. If Taxes are paid to a tax authority, each Party will provide the other such assistance as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid. In the event that the governing tax authority retroactively determines that a payment made by a Party to the other pursuant to this Agreement should have been subject to withholding (or to additional withholding) for Taxes, and such Party (the *"Withholding Party"*) remits such withholding Taxes to the tax authority, the Withholding Party will have the right to offset such amount, including any interest and penalties that may be imposed thereon (except to the extent any such interest or penalties result from the negligence of the Withholding Party), against future payment obligations of the Withholding Party under this Agreement (or, at the option of the Withholding Party, the Withholding Party will have the right to invoice the other Party for such amount, and the other Party will pay such amount within sixty (60) days of the receipt of such invoice); *provided*, that the Withholding Party may also pursue reimbursement by any other available remedy.

8.6.2. *Indirect Taxes*. All payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any payments, the paying Party shall pay such Indirect Taxes at the applicable rate in respect of such payments following receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by the receiving Party in respect of those payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes. If such amounts of Indirect Taxes are refunded by the applicable Governmental Authority or other fiscal authority subsequent to payment, the Party receiving such refund will transfer such amount to the paying Party within forty-five (45) days of receipt.

8.6.3. *Employee Taxes*. Each Party shall be responsible for taxes based on, imposed on or calculated by reference to any employees employed by that Party.

8.6.4. *Imports.* For the avoidance of doubt, the Parties acknowledge and agree that none of the upfront payment or royalties payable under this Agreement are related to the license (or right) to import or any import of Products. The Parties shall cooperate in accordance with Applicable Laws to ensure where permissible no import duties are paid on imported Product. The Parties shall cooperate to ensure that the Party responsible for shipping values clinical Product in accordance with Applicable Laws and minimises where permissible any such duties and any related import taxes that are not reclaimable from the relevant authorities. The receiving Party shall be responsible for any import clearance, including payment of any import duties and similar charges, in connection with any Products transferred to such Party under this Agreement.

8.6.5. *Payment Flows.* The Parties recognize that this Agreement is global in nature and does not set out in detail how the financial flows will be implemented at a legal entity level in order to achieve the economic sharing of profits and losses generated by the Products as set forth in this Agreement. At least eighteen (18) months prior to first commercial launch of a Product, the Parties will discuss and agree upon the principles for such profit and loss sharing at a legal entity level. The Parties will use reasonable efforts to minimize the impact on both Parties of irrecoverable and/or non-creditable Indirect Taxes, including, where appropriate, causing their local Affiliates to enter into a "Marketing Services Agreement" with one another or otherwise discussing how to address the issue. For clarity, the provisions of this Section 8.6.5 (Payment Flows) will in no way change the allocation between the Parties of Development Costs and General Costs set forth in Section 7.2.8.1 (Costs) or of Net Revenues set forth in Section 7.2.8.2 (Profits).

8.7. Late Payment. Any payments or portions thereof due hereunder which are not paid when due will bear interest at the Contract Interest Rate, compounded annually, calculated on the number of days such payment is delinquent. This Section 8.7 (Late Payment) will in no way limit any other remedies available to either Party.

8.8. Change in Accounting Periods. From time to time, either of the Parties may change its accounting and financial reporting practices from calendar quarters and calendar years to fiscal quarters and fiscal years or vice versa. If a Party notifies the other in writing of a change in its accounting and financial reporting practices from calendar quarters and calendar years to fiscal quarters and fiscal years or vice versa, then thereafter, beginning with the period specified in the notice, the Parties will cooperate to determine a way to report and reconcile each Party's accounting periods so as to facilitate payments to be made hereunder.

9. DISTRACTING PRODUCTS

9.1. Distracting Program. Except as set forth in Sections 9.2 (Post-Effective Date Affiliates), 9.3 (Termination, Divestiture or Inclusion) and 9.4 (Pre-Clinical Research and Development Programs):

9.1.1. Partner will not, during the Term and, other than in the event of termination by Partner pursuant to Section 14.3 (Termination for Breach), for [*] thereafter, itself or through its Affiliates, conduct or participate in, or advise, assist or intentionally enable any Third Party to conduct or participate in, any Distracting Program anywhere in the world; *provided*, that [*];

9.1.2. Amgen will not, during the Term, itself or through its Affiliates, conduct or participate in, or advise, assist or intentionally enable any Third Party to conduct or participate in, any Distracting Program in the Collaboration Territory; and

9.1.3. [*].

9.2. Post-Effective Date Affiliates. If a Party enters into a Distracting Transaction then it will provide notice to the other Party, within [*] business days after the closing of the Distracting Transaction, describing in reasonable detail, to the extent permitted by Applicable Law and without disclosing any proprietary information, the Distracting Program. During the pendency of any potential Distracting Transaction, and until the provisions of Section 9.3 (Termination, Divestiture or Inclusion) are fully implemented, the Party entering into the Distracting Transaction will Segregate the Distracting Program from programs for the Products.

9.3. Termination, Divestiture or Inclusion. The notice provided pursuant to Section 9.2 (Post-Effective Date Affiliates) will include a notification as to whether the Party entering into the Distracting Transaction intends to Divest, terminate or include in the collaboration the Distracting Program in accordance with this Section 9.3 (Termination, Divestiture or Inclusion):

9.3.1. *Divestiture.* If a Party elects to Divest the Distracting Program, then it will Segregate such Distracting Program from the programs for the Products and Divest such Distracting Program within [*] months of the closing of the Distracting Transaction. The divesting Party and its Affiliates (including the Affiliate with the Distracting Program) will not directly or indirectly assert any intellectual property or proprietary right embodied in the Distracting Program and under the control of the divesting Party or its Affiliates as a result of the Distracting Transaction, against or with respect to Products or otherwise obstruct the Parties' (or their Affiliates, sublicensees', contractors' or agents') efforts under this Agreement or, if Partner is the divesting Party, Amgen's (or its Affiliates, sublicensees', contractors' or agents') efforts with respect to Products in the Excluded Territory. If the divesting Party fails to complete a divestiture of the Distracting Program within [*] months of the closing of the Distracting Transaction, then such Party will be deemed to have chosen to terminate the Distracting Program, effective as of such [*] month anniversary, and will promptly comply with the requirements of Section 9.3.2 (Termination); *provided*, that if at the expiration of such [*] month period, the divesting Party has agreed terms with a Third Party to Divest the Distracting Program then such [*] month period will be extended as required for the divesting Party and such Third Party to consummate the transaction, but in no event will such extension exceed an additional [*] days.

9.3.2. *Termination.* If a Party elects to terminate such Distracting Program, it will terminate all activities of such Distracting Program within [*] days after the closing of the Distracting Transaction, during which period it will Segregate such Distracting Program from the programs for the Products. The terminating Party and its Affiliates will not directly or indirectly assert any intellectual property or proprietary right of the Distracting Program against or with respect to Products or otherwise to obstruct the Parties' (or their Affiliates, sublicensees', contractors' or agents') efforts under this Agreement or if Partner is the terminating Party, Amgen's (or its Affiliates, sublicensees', contractors' or agents') efforts with respect to Products in the Excluded Territory during such termination period or thereafter.

9.3.3. *Inclusion.* If a Party elects to include the Distracting Program in the collaboration, then such Party (the "*Distracting Transaction Party*") will provide written notice within [*] days after the closing of the Distracting Transaction of such election to the other Party, together with a non-confidential summary of the related Distracting Program. If the non-Distracting Transaction Party desires to evaluate such Distracting Program, then the non-Distracting Transaction Party will notify the Distracting Transaction Party within [*] days of its receipt of such notice. Promptly after the Distracting Transaction Party's receipt of such evaluation notice, the Distracting Transaction Party will provide the non-Distracting Transaction Party with a confidential summary of the Distracting Program, including material pre-clinical and clinical data and proposed development plan and budget (as well as such other information that the non-Distracting Transaction may reasonably request), which summary will be deemed to be Confidential Information of the Distracting Transaction Party under this Agreement (and the non-Distracting Transaction Party shall be

entitled to use such information solely for the purpose of evaluating whether to include such Distracting Program in the collaboration). Within [*] days of its receipt of such summary, the non-Distracting Transaction Party will notify the Distracting Transaction Party of its election to either (i) include the Distracting Program in the collaboration or (ii) decline to include such Distracting Program in the collaboration. If the non-Distracting Transaction Party agrees in writing to include such Distracting Program in the collaboration, then (a) the Distracting Program will be included under the terms of this Agreement and all the technology, intellectual property and tangible materials (including biological compounds, chemical compounds, intermediates, assays, screens, animal models and reagents) of such Distracting Program will be considered within the Product Intellectual Property; (b) the Distracting Products included in the Distracting Program will be deemed Products hereunder; (c) a JPT will be formed for each such Distracting Product and each such JPT will develop a Development Plan and Development Budget for each Distracting Product, for review and approval by the JSC; (d) all Development Costs, General Costs and profits with respect to each such Distracting Product [*]; and (e) the Parties will enter into an amendment or supplement to this Agreement to the extent necessary to specify which Party will be the Development Lead, Manufacturing Lead, and Commercial Lead, plus such other changes, modifications and assignments as are reasonably necessary to effectuate the addition of such Distracting Product. If the non-Distracting Transaction Party does not agree to include such Distracting Program in the collaboration, then (i) from and after the date of such election, the obligations of the Distracting Transaction Party set forth in Section 9.1 (Distracting Program) will no longer apply with respect to such Distracting Program, and (ii) the non-Distracting Party shall destroy the confidential summary of the Distracting Program provided to it by the Distracting Transaction Party (*provided*, that the non-Distracting Party shall be entitled to retain one (1) copy of such information for its record-keeping purposes).

9.4. Pre-Clinical Research and Development Programs. Notwithstanding anything in this Article 9 (Distracting Products), either Party will have the right, either itself or through its Affiliates, to conduct non-clinical research and non-clinical development on any Distracting Product, subject to this Section 9.4 (Pre-Clinical Research and Development). At least [*] days prior to the anticipated initiation of the first [*] for such Distracting Product, the Party conducting such activities (the *"Researching Party"*) will notify the non-Researching Party and provide a non-confidential summary of the related Distracting Program to the non-Researching Party (*"Program Notice"*). If the non-Researching Party desires to evaluate such Distracting Program, then the non-Researching Party will notify the Researching Party within thirty (30) days of its receipt of the Program Notice. Promptly after the Researching Party's receipt of such evaluation notice, the Researching Party will provide the non-Researching Party with a confidential summary of the Distracting Program, including material pre-clinical data and proposed development plan and budget (as well as such other information that the non-Researching Party may reasonably request), which summary will be deemed to be Confidential Information of the Researching Party under this Agreement (and the non-Researching Party shall be entitled to use such information solely for the purpose of evaluating whether to include such Distracting Program in the collaboration). Within [*] days of its receipt of such summary, the non-Researching Party will notify the Researching Party of its election to either (i) include the Distracting Program in the collaboration, in which case the terms of Section 9.3.3 (Inclusion) will apply with respect to such Distracting Program (*provided*, that the Researching Party will be entitled to receive a [*]) or (ii) decline to include such Distracting Program in the

collaboration. If the non-Researching Party declines to include such Distracting Program in the collaboration, then (i) from and after the date of such election, the obligations of the Researching Party set forth in Section 9.1 (Distracting Program) will no longer apply with respect to such Distracting Program, and (ii) the non-Researching Party shall destroy the confidential summary of the Distracting Program provided to it by the Researching Party (*provided*, that the non-Research Party shall be entitled to retain one (1) copy of such information for its record-keeping purposes).

9.5. Reasonable Restrictions. Each of the Parties acknowledges the provisions of this Article 9 (Distracting Products) are reasonable and necessary to protect the legitimate interests of the other Party and to encourage the free sharing of information between the Parties with respect to Products, and each of the Parties agrees not to contest such limitations in any proceeding. Each Party acknowledges that the other Party would not have entered into this Agreement absent the restrictions set forth in this Article 9 (Distracting Products) and that a breach or threatened breach of this Article 9 (Distracting Products) would be likely to result in irreparable harm to such Party for which there is no adequate remedy at law. Therefore, the Parties will be entitled to obtain from any court of competent jurisdiction injunctive relief, specific performance, and an equitable accounting of any earnings, profits or benefits arising out of any such breach without the requirement to post a bond or to demonstrate irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 9.5 (Reasonable Restrictions) is intended or will be construed to limit in any way either Party's right to equitable relief or any other remedy for breach of this or any other provision of this Agreement.

10. INTELLECTUAL PROPERTY

10.1. Invention Ownership. Each Party will own all right, title, and interest in and to all Inventions that are made by or on behalf of such Party, solely or independent of the other Party, and all intellectual property rights related thereto, and any Invention that is jointly made will be owned jointly by the Parties. Inventorship will be determined according to United States Patent Law (without reference to any conflict of law principles).

10.2. Copyright Ownership; Certain Confidential Information. Each Party will own all right, title, and interest in and to all Copyrights created pursuant to this Agreement that are authored by or on behalf of such Party, solely or independent of the other Party, and all intellectual property rights related thereto. The Parties will jointly own all right, title, and interest in and to all Copyrights created pursuant to this Agreement that are authored by or on the behalf of the Parties jointly, and all intellectual property rights related thereto. Notwithstanding the foregoing, any Copyrights pertaining to Promotional Materials or training materials for a Product will be owned solely by the Commercial Lead for such Product.

10.3. Joint Ownership. Except as expressly provided in this Agreement, it is understood that neither Party will have any obligation to obtain any approval or consent of, nor pay a share of the proceeds to or account to, the other Party to practice, enforce, license, assign or otherwise exploit Inventions or intellectual property (including Copyrights and Product Trademarks) owned jointly by the Parties hereunder, and each Party hereby waives any right it may have under the laws of any jurisdiction to require such approval, consent or accounting. Each Party agrees to cooperate with the other Party, as reasonably requested, and to take such actions as may be required to give effect to this Section 10.3 (Joint Ownership) in a particular country within the Collaboration Territory.

10.4. License Grant by Amgen. Amgen hereby grants and causes its Affiliates to grant to Partner during the Term a [*], fully-paid, royalty-free license to Amgen Intellectual Property and Program Intellectual Property solely (i) to the extent necessary to conduct the Designated Partner Activities and (ii) to exercise and perform Partner's other rights and obligations under the terms of this Agreement. Such license is sublicensable by Partner or its Affiliates solely in accordance with Section 6.4 (Use of Affiliates and Third Party Contractors).

10.5. License Grant by Partner. Partner hereby grants and causes its Affiliates to grant to Amgen and its Affiliates a [*], fully-paid, royalty-free license to Partner Intellectual Property and Program Intellectual Property solely (i) to the extent necessary to conduct the Designated Amgen Activities and (ii) to exercise and perform Amgen's other rights and obligations under the terms of this Agreement. The foregoing license is sublicensable by Amgen or its Affiliates in accordance with Section 6.4 (Use of Affiliates and Third Party Contractors). Additionally, Partner hereby grants and causes its Affiliates to grant to Amgen and its Affiliates a [*], irrevocable, fully-paid, royalty-free, world-wide license to Partner Intellectual Property and Program Intellectual Property solely to use, make, have made, sell, offer for sale and import Products for all uses in the Excluded Territory (which license is sublicensable by Amgen or its Affiliates to Third Parties to whom Amgen or its Affiliates also grant a license in the Excluded Territory to Know-How or Patents owned or controlled by Amgen with respect to Product(s) , or the manufacture, formulation or use thereof; [*]).

10.6. Prosecution and Maintenance.

10.6.1. *Amgen Intellectual Property*. Subject to the provisions of Section 2.10 (Patent Coordinators), Amgen will control, itself or through outside counsel, and have final decision making authority (after consultation with Partner in accordance with the terms and conditions of this Agreement) with respect to the Prosecution and Maintenance of the Patents within the Amgen Intellectual Property in the Collaboration Territory that claim a Product, and with respect to preparation and filing for any Patent Extensions.

10.6.2. *Partner Intellectual Property*. Subject to the provisions of Section 2.10 (Patent Coordinators), Partner will control, itself or through outside counsel, and have final decision making authority (after consultation with Amgen in accordance with the terms and conditions of this Agreement) with respect to the Prosecution and Maintenance of the Patents within the Partner Intellectual Property in the Collaboration Territory that claim a Product, and with respect to preparation and filing for any Patent Extensions.

10.6.3. *Program Intellectual Property*. Subject to the provisions of Section 2.10 (Patent Coordinators), Amgen will have the first right (but not the obligation) to control, through outside counsel, and have final decision making authority (after consultation with Partner in accordance with the terms and conditions of this Agreement) with respect to the Prosecution and Maintenance of the Patents and Product Trademarks within the Program Intellectual Property (the *"Program Patents and Trademarks"*), and with respect to preparation and filing for any Patent Extensions. If Amgen desires to abandon the prosecution of a Program Patent or Trademark, then it will inform Partner thereof in writing with sufficient advance notice to reasonably enable Partner to assume the filing or prosecution of such Program Patent or Trademark (but in no event later than [*] days prior to the next deadline for any action that may be taken with respect such Program Patent or Trademark with the U.S. Patent and Trademark Office or any non-U.S. patent office) at Partner's non-reimbursable cost.

10.6.4. *Review and Comment Rights - Patents*. Through the Patent Coordinators: (i) the filing Party will provide the non-filing Party with copies of and an opportunity to review and comment upon the text of the applications relating to the applicable Patents at least [*] days before filing; *provided*, that if it is not reasonably practicable to provide such application in such [*] day period, then the filing Party will provide either a draft copy of such application or a statement of intent to file such application in such [*] day period; (ii) the filing Party will provide the non-filing Party with a copy of each submission made to and document received from a patent authority, court or other tribunal regarding any Patent reasonably promptly after making such filing or receiving such document, including a copy of each application for each Patent as filed together with notice of its filing date and application number; (iii) the filing Party will keep the non-filing Party advised of the status of all material communications, and actual and prospective filings or submissions regarding the Patents, and will give the non-filing Party copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (iv) the filing Party will consider in good faith the non-filing Party's comments on such communications, filings and submissions for the Patents. With respect to any filings or other materials provided to the non-filing Party under this Section 10.6 (Prosecution and Maintenance), the filing Party will have the right to redact any manufacturing information and any information relating to any product other than Products from any such filings and materials. Either Patent Coordinator may escalate to the JSC whether to obtain any license to Third Party Patents or Know-How; *provided*, that in the event of a disagreement at the JSC with respect to such decision, Amgen will make the final decision with respect thereto.

10.6.5. *Review and Comment Rights - Product Trademarks.* Through the Patent Coordinators: (i) the filing Party will provide the non-filing Party with copies of and an opportunity to review and comment upon the text of each application relating to registration of a Product Trademark at least [*] business days before filing; (ii) the filing Party will provide the non-filing Party with a copy of each submission made to and document received from a trademark registration authority, court or other tribunal regarding any Product Trademark reasonably promptly after making such filing or receiving such document, including a copy of each application for registration of each Product Trademark as filed together with notice of its filing date and application number; (iii) the filing Party will keep the non-filing Party advised of the status of all material communications, and actual and prospective filings or submissions regarding the application for registration of Product Trademarks, and will give the non-filing Party copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any trademark registration authority or judicial body; and (iv) the filing Party will consider in good faith the non-filing Party's comments on such communications, filings and submissions for the Product Trademarks.

10.7. Defense and Settlement of Third Party Claims of Infringement. If a Third Party asserts that Patents, Know-How or other rights owned or controlled by it are infringed by the activities hereunder of either of the Parties, then defense of such claim (an "*Infringement Claim*") will be managed in accordance with the provisions of Section 13.4 (Defense of Third Party Claims), with coordination and cooperation between the Defending Party and Assisting Party occurring via the Patent Coordinators. If either Party seeks to initiate a nullification, declaratory judgment, revocation, or opposition proceeding against any such Patents, Know-How or other rights in response to

prospective or actual Third Party Claims of Infringement, the Parties will coordinate and cooperate in regard to such proceedings in accordance with the procedures set forth in Section 13.4 (Defense of Third Party Claims), with coordination and cooperation between the Defending Party and Assisting Party occurring via the Patent Coordinators.

10.8. Enforcement. Except as expressly set forth in this Section 10.8 (Enforcement), each Party will retain all its rights to control the enforcement of its own intellectual property. Amgen will have the first right (but not the obligation) to enforce the Program Intellectual Property against any Third Party that is developing, manufacturing, selling, or importing a product or service that competes with a Product; *provided*, that Partner will have the right to approve in writing any settlement of any claim, suit or action involving its intellectual property that admits the invalidity or unenforceability of its intellectual property or imposes on Partner restrictions or obligations. If Amgen fails to bring any such action or proceeding within forty-five (45) days (or twenty-five (25) days in the case of an action brought under the Biologics Price Competition and Innovation Act of 2009 (or any amendment or successor statute thereto) or within the time frame of any other relevant regulatory or statutory framework that may govern) of a request by Partner to do so (or, if sooner, five (5) days before the time limit, if any, set forth in the relevant laws and regulations for the filing of such actions), or earlier notifies Partner in writing of its intent not to bring such action or proceeding, then Partner will have the right (but not the obligation) to bring any such action or proceeding by counsel of its own choice; *provided*, that Amgen will have the right to approve in writing any settlement of any claim, suit or action involving its intellectual property that admits the invalidity or unenforceability of its intellectual property or imposes on Amgen restrictions or obligations. The non-enforcing Party will reasonably assist the enforcing Party with respect to any such enforcement in the Collaboration Territory, including, in the event that it is determined that the non-enforcing Party is an indispensable Party to such action, by being named as a Party in such action, and cooperate in any such action at the enforcing Party's request. Without limiting the foregoing, the enforcing Party will keep the non-enforcing Party advised of all material communications, actual and prospective filings or submissions regarding such action, and will provide the non-enforcing Party copies of and an opportunity to review and comment on any such material communications, filings and submissions (*provided*, that the enforcing Party will have the right to redact any manufacturing information and any information relating to any product other than Products from any such materials). All Recoveries will be retained by or paid to Amgen (whether Amgen is the enforcing Party or not), but to the extent such Recoveries were obtained with respect to a Product or a product that competes directly with a Product, the same shall be included in Net Revenues for the period in which such Recovery is made.

10.9. Patent Term Extensions. Each non-filing Party will provide reasonable assistance to the filing Party in connection with obtaining supplementary protection certificates, patent term extensions or similar protection for Patents ("*Patent Extensions*") within the Product Intellectual Property or otherwise licensed or assigned hereunder as determined by the Patent Coordinators. To the extent reasonably and legally required to obtain any such Patent Extensions in a particular country, the non-filing Party will make available to the filing Party copies of all necessary documentation to enable the filing Party to use the same for the purpose of obtaining Patent Extensions in such country. Notwithstanding Section 10.6 (Prosecution and Maintenance) above, the Patent Coordinator for the Commercial Lead will have the right to make the final decision as to which Patents within the Amgen Intellectual Property, Partner Intellectual Property or Program Intellectual Property will be extended with respect to the Product(s) for which such Party is the Commercial Lead.

10.10. Trademarks.

10.10.1. *Title*. The Parties will jointly own all right, title and interest in and to the Product Trademarks unless the local laws of any country prohibit joint ownership in which case Amgen shall own the Product Trademarks in those countries. Neither Party will, and will ensure that its Affiliates do not: (i) challenge any Product Trademark or the registration thereof in any country; (ii) file, register or maintain any registrations for any trademarks or trade names that are confusingly similar to any Product Trademark (other than for a Product), in any country without the express prior written consent of the other Party; or (iii) authorize or assist any Third Party to do the foregoing.

10.10.2. *Required Use and Compliance*.

10.10.2.1. Promotional Materials and all packaging and package inserts for Products in the Collaboration Scope will display the Amgen Housemarks and the Partner Housemarks to the extent allowed by Applicable Law and in accordance with the Brand Plan. Except for the use of the Amgen Housemarks and the Partner Housemarks as may be expressly set forth in the Brand Plan, each Party will promote Products in the Collaboration Scope only under the Product Trademarks.

10.10.2.2. Each Party agrees that it and its Affiliates will: (i) ensure that each use of the Product Trademarks and the other Party's Housemarks by such Party is accompanied by an acknowledgement that such Product Trademarks are jointly owned and such Housemarks are owned by the other Party; (ii) not use such Product Trademarks or the other Party's Housemarks in a way that might materially prejudice their distinctiveness or validity or the goodwill of the other Party therein; and (iii) not use any trademarks or trade names so resembling any of such Product Trademarks or the other Party's Housemarks as to be likely to cause confusion or deception.

10.10.3. *Housemark Licenses*.

10.10.3.1. **To Partner**. Amgen hereby grants to Partner a [*], royalty-free license to use the Amgen Housemarks solely as set forth in the Promotional Materials and other materials provided to it by Amgen, and solely to develop, manufacture and commercialize Products in the Collaboration Scope in accordance with the Brand Plan, Country Plans and this Agreement.

10.10.3.2. **To Amgen**. Partner hereby grants to Amgen a [*], royalty-free license to use the Partner Housemarks solely as set forth in the Promotional Materials and other materials provided to it by Partner, and solely to develop, manufacture and commercialize Products in the Collaboration Scope in accordance with the Brand Plan, Country Plans and this Agreement.

10.10.1. *Respect of Trademarks*. Partner will not have, assert or acquire any right, title or interest in or to any Amgen Housemarks or the goodwill pertaining thereto, and Amgen will not have, assert or acquire any right, title or interest in or to any Partner Housemarks or the goodwill pertaining thereto, in each case by means of entering into or performing under this Agreement, except in each case for the limited licenses explicitly provided in this Agreement.

10.10.2. *Infringement.* Each Party will monitor the Product Trademarks against infringing uses within the Collaboration Scope and will promptly notify the other Party of any infringement or threatened infringement of any of the Product Trademarks of which it becomes aware. The Patent Coordinators will

determine what action, if any, to take in response to any such infringement or threatened infringement of any Product Trademark.

11. CONFIDENTIALITY, PUBLICATIONS AND PRESS RELEASES

11.1. Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [*] years thereafter, the receiving Party will keep confidential and will not publish or otherwise disclose or use for any purpose any and all information or materials related to the activities contemplated hereunder that is furnished to it by the other Party pursuant to this Agreement and is identified by the disclosing Party as confidential, proprietary or the like or that the receiving Party has reason to believe is confidential based upon its own similar information (collectively, *"Confidential Information"*). For clarity, except for rights expressly granted herein, both Parties will have no right to and will not utilize any Confidential Information of the other Party for activities outside the Collaboration Scope or for activities related to products other than the Products. Notwithstanding the foregoing, Confidential Information will not include any information to the extent that it can be established by written documentation by the receiving Party that such information:

11.1.1. was obtained or was already known by the receiving Party or its Affiliates without obligation of confidentiality as a result of disclosure from a Third Party that the receiving Party did not know was under an obligation of confidentiality to the disclosing Party with respect to such information;

11.1.2. was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party through no act or omission of the receiving Party or its Affiliates in breach of this Agreement;

11.1.3. became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliates in breach of this Agreement; or

11.1.4. was independently discovered or developed by the receiving Party or its Affiliates (without reference to or use of Confidential Information of the disclosing Party).

11.2. Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) as reasonably necessary in conducting the activities contemplated under this Agreement; (ii) with respect to Confidential Information generated in the course of the activities conducted hereunder, to the extent pertaining specifically to a Product, for use by Amgen in connection with a Product in the Excluded Territory or disclosure by Amgen to a partner or licensee for use with respect to a Product in the Excluded Territory; (iii) to the extent such disclosure is to a Governmental Authority, as reasonably necessary in filing or prosecuting patent, copyright and trademark applications in accordance with this Agreement, prosecuting or defending litigation in accordance with this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement, filing Regulatory Filings, obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for a Product, or otherwise required by Applicable Law, *provided*, that if a Party is required by Applicable Law to make any such disclosure of the other Party's Confidential Information it will, except where impracticable for necessary disclosures (for example, in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and, in the case of each of the foregoing exceptions pursuant to this subsection (iii), will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; (iv) to advisors

(including lawyers and accountants) on a need to know basis in support of the purposes of this Agreement, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement; and (v) to the extent mutually agreed to by the Parties. Neither Party will disclose Confidential Information of the other Party to its personnel or to an Affiliate except to the extent such personnel or Affiliate needs to know such information for the performance of such Party's activities hereunder.

11.3. Confidential Treatment of Terms and Conditions. The Parties agree that the terms and conditions of this Agreement will be Confidential Information of each Party, and such material terms and conditions will not be disclosed, except (i) as otherwise permitted under Section 11.2 (Authorized Disclosure) and (ii) if required by Applicable Law (including disclosure of a redacted version of this Agreement in a relevant SEC filing). Notwithstanding the foregoing, with respect to complying with the disclosure requirements of any Governmental Authority in connection with any required filing of this Agreement, the Parties will consult with one another concerning which terms of this Agreement will be requested to be redacted in any public disclosure of this Agreement, and in any event each Party will seek reasonable confidential treatment for any public disclosure by any such Governmental Authority.

11.4. Press Releases. Notwithstanding Section 11.3 (Confidential Treatment of Terms and Conditions), the Parties will issue a joint press release to announce the execution of this Agreement, which is attached hereto as the Press Release Schedule (or such other joint press release as may be mutually agreed upon in writing by the Parties) and is for use in responding to inquiries about this Agreement. Thereafter, Partner and Amgen may each disclose to Third Parties (including media interviews and disclosures to financial analysts) the information contained in such press release (but only such information) without the need for further approval by the other; *provided*, that such information is still accurate. Each Party will have the right to issue additional press releases and disclosures in regards to the terms of this Agreement only with the prior written consent of the other Party, such consent not to be unreasonably withheld (or as required to comply with Applicable Law). For any such proposed press release or disclosure, the disclosing Party will provide [*] business days' notice to the other Party and will reasonably consider the other Party's comments that are provided within [*] business days after such notice, or such shorter notice and comment periods as are reasonably required under the circumstances but not less than [*] business days.

11.5. Prior Agreement. This Agreement supersedes the Confidential Disclosure Agreement between Amgen and MedImmune, LLC (an Affiliate of AstraZeneca) dated September 14, 2011, as amended and supplemented, including any written requests thereunder with respect to information disclosed thereunder relating to the Products and activities related thereto. All confidential information exchanged between the Parties and their respective Affiliates under such agreement will be deemed Confidential Information of the disclosing Party disclosed hereunder and will be subject to the terms of this Agreement.

11.6. Publications and Program Information. Except as permitted pursuant to Section 3.5 (Clinical Trial Register), the Development Lead for a Product will have the sole right to publish and make scientific presentations with respect to such Product, and to issue press releases (except with respect to the terms of this Agreement, which is governed by Section 11.4 (Press Releases)) or make other public disclosures regarding any such Product (including with respect to its development, commercialization and regulatory matters), and the other Party will not do so without the Development Lead's prior written consent, except as required by Applicable Law; *provided*, that any publication or presentation to be made by the Development Lead that names the other Party will

require the prior consent of the other Party. The Development Lead will keep the relevant committee or team informed of its general publication strategy and presentation calendar. The Development Lead will consider any reasonable comments regarding such strategy from the other Party. In addition, the Development Lead will deliver to the other Party a copy of any proposed written publication or outline of presentation to be made by the Development Lead with respect to any scientific data pertaining to a Product in the Collaboration Scope in advance of submission for publication or presentation at least [*] days in advance of submission (or, where a copy of such publication or presentation is not available at such time, a draft or outline of such publication or a description of such presentation), and the other Party will have the right to: (i) require a delay in submission of not more than [*] days to enable patent applications protecting the other Party's rights in Inventions owned by such Party; and (ii) prohibit disclosure of any of its Confidential Information in any such proposed publication or presentation. Publications and presentations will be subject to policies mutually agreed by the Patent Coordinators to ensure appropriate protection of intellectual property rights. If there is any dispute between the Parties with regard to a proposed publication, presentation or other communication regarding this Agreement, such dispute shall be referred to the JSC for resolution (with the Development Lead for the Product having the final decision).

12. REPRESENTATIONS AND WARRANTIES

12.1. Mutual Representations and Warranties. Each of the Parties hereby represents and warrants, as of the Effective Date to the other Party as follows:

12.1.1. It is duly organized and validly existing under the Applicable Law of its jurisdiction of incorporation and it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;

12.1.2. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement, and compliance with its terms and provisions, and the consummation of the transaction contemplated hereby, by such Party will not materially conflict, interfere or be inconsistent with, result in any material breach of or constitute a material default under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor to its knowledge violate any Applicable Law. The person or persons executing this Agreement on such Party's behalf have been duly authorized to do so by all requisite corporate action;

12.1.3. It has not been debarred or the subject of debarment proceedings by any Governmental Authority;

12.1.4. To its knowledge, it and its Affiliates have not violated any Anti-Corruption Law; and

12.1.5. It has not granted any right to any Third Party relating to any intellectual property or proprietary right licensed, granted or assigned by it to the other Party hereunder that conflicts with the rights licensed, granted or assigned to the other Party hereunder.

12.2. Amgen Representations and Warranties. In addition to the representations and warranties set forth in Section 12.1 (Mutual Representations and Warranties), Amgen hereby represents and warrants to Partner that, as of the Effective Date:

12.2.1. Amgen has not received written notice from any Third Party that any issued and enforceable Patent of such Third Party would be infringed by the importation, manufacture, distribution, marketing or sale of a Product (except, in each case, where Amgen may have since such time obtained a license to the relevant Patent);

12.2.2. Amgen is the sole owner of all right, title and interest in the Patents included within Amgen Intellectual Property or otherwise has the right to grant to Partner the rights to such Patents, and the Amgen Intellectual Property is not subject to any lien or other encumbrance in favor of any Third Party that conflicts with the rights or licenses of Partner hereunder;

12.2.3. No patent application or registration within the Amgen Intellectual Property is the subject of any pending interference, opposition, cancellation, or patent protest pursuant to 37 C.F.R. §1.291;

12.2.4. To Amgen's knowledge, no Third Party is [*] in the Collaboration Scope;

12.2.5. To Amgen's knowledge, the development of the Products in the Collaboration Scope by or on behalf of Amgen [*];

12.2.6. To Amgen's knowledge, there is no [*]. For the purposes of this Section 12.2.6, "[*]" does not include claims for [*] for the [*] related to [*];

12.2.7. Amgen has made available to Partner true and correct copies of the following: (i) all material Regulatory Filings for the Collaboration Territory; (ii) all material correspondence with Governmental Authorities with respect to such Regulatory Filings; (iii) all minutes of any material meetings, telephone conferences or discussions with Governmental Authorities with respect to such Regulatory Filings; and (iv) all final clinical trial reports, in each case with respect to the Products and to the extent in existence as of the Effective Date;

12.2.8. Amgen is the owner of [*] Regulatory Filings for the Products in the Collaboration Scope;

12.2.9. Except as would not be reasonably expected to have a material adverse effect on the development, manufacture or commercialization of Products, Amgen has filed with the relevant Governmental Authorities all required notices, amendments and annual reports, as well as adverse event reports, with respect to the Regulatory Filings for the Products in the Collaboration Scope in existence as of the Effective Date;

12.2.10. To Amgen's knowledge, there is no pending action or action threatened in writing by relevant Governmental Authorities to place a clinical hold order on, or otherwise terminate or suspend, any of the Regulatory Filings for a Product in existence as of the Effective Date;

12.2.11. The Completed Clinical Trials Schedule contains a complete list of all clinical trials carried out by or on behalf of Amgen or its Affiliates in relation to the Products for which dosing of patients was completed before the Effective Date;

12.2.12. Amgen has provided Partner with true and correct copies of [*];

12.2.13. No written notice has been given or received by Amgen that [*] prior to the Effective Date; and

12.2.14. Amgen has [*].

12.3. Mutual Covenants. Each Party hereby covenants to the other Party that, during the Term:

12.3.1. it will not grant any right to any Third Party relating to any intellectual property or proprietary right licensed or assigned by it to the other Party hereunder that conflicts with the rights granted to the other Party hereunder;

12.3.2. it will not knowingly use in connection with the research, development, manufacture or commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been debarred or the subject of debarment proceedings by any regulatory agency; and

12.3.3. Each Party agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants and subcontractors hired in connection with the subject matter of his Agreement (together with the Party, the "*Party Representatives*") that in connection with any Designated Partner Activities or Designated Amgen Activities, as applicable:

12.3.3.1. Each Party's respective Party Representatives shall not directly or indirectly pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give, or authorize the giving of anything else of value, to:

(i) any Government Official in order to influence official action;

(ii) any Person (whether or not a Government Official) (a) to influence such Person to act in breach of a duty of good faith, impartiality or trust ("acting improperly"), (b) to reward such Person for acting improperly, or (c) where such Person would be acting improperly by receiving the money or other thing of value;

(iii) any other Person while knowing or having reason to know that all or any portion of the money or other thing of value will be paid, offered, promised or given to, or will otherwise benefit, a Government Official in order to influence official action for or against either Party in connection with the matters that are the subject of this Agreement; or

(iv) any Person to reward that Person for acting improperly or to induce that Person to act improperly.

12.3.3.2. Each Party's Party Representatives shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws.

12.3.3.3. Each Party, on behalf of itself and its other Party Representatives, represents and warrants to the other Party that for the term of this Agreement and [*] thereafter each Party shall maintain accurate books and reasonably detailed records in connection with the performance of its obligation under this Agreement including all records required to establish compliance with Sections 12.3.3.1 and 12.3.3.2 above.

12.3.3.4. Each Party shall promptly provide the other Party with written notice of the following events:

(a) Upon becoming aware of any breach or violation by a Party or its Party Representative of any representation, warranty or undertaking set forth in Sections 12.3.3.1 and 12.3.3.2.

(b) Upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of its Party Representatives connected with this Agreement that any of them is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation.

12.4. Amgen Covenant. Except as would not be reasonably expected to have a material adverse effect on the development, manufacture or commercialization of Products, Amgen and its Affiliates will [*]. Amgen will notify Partner in writing of any [*].

12.5. AstraZeneca Covenant. [*].

12.6. Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 12 (REPRESENTATIONS AND WARRANTIES), PARTNER AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE COLLABORATION, PRODUCT INTELLECTUAL PROPERTY, AMGEN HOUSEMARKS, PARTNER HOUSEMARKS, PRODUCT TRADEMARKS, THIS AGREEMENT, OR ANY OTHER SUBJECT MATTER RELATING TO THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.

12.7. Limitation of Liability. NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN, OTHER THAN TO THE EXTENT RESULTING FROM A PARTY'S BREACH OF ARTICLE 9 (DISTRACTING PRODUCTS) OR SECTION 11.1 (CONFIDENTIALITY; EXCEPTIONS), IN NO EVENT WILL PARTNER OR AMGEN BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT. THE FOREGOING SENTENCE WILL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST SUCH DAMAGES AS ARE AWARDED TO A THIRD PARTY WITH RESPECT TO THIRD PARTY CLAIMS UNDER SECTION 13.1 (INDEMNITY BY PARTNER) OR SECTION 13.2 (INDEMNITY BY AMGEN).

13. INDEMNIFICATION AND INSURANCE

13.1. Indemnity by Partner. Partner will defend, indemnify, and hold harmless Amgen, its Affiliates, and their respective directors, officers, employees, agents and representatives (collectively, *"Amgen Indemnitees"*), at Partner's cost and expense, from and against any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and attorneys' fees) (collectively, *"Losses"*) arising out of any Third Party Claims brought against any Amgen Indemnitee to the extent such Losses result from: [*]. The indemnification obligations under this Section 13.1 (Indemnity by Partner) exclude Losses to the extent they arise from [*] below in Section 13.2 (Indemnity by Amgen).

13.2. Indemnity by Amgen. Amgen will defend, indemnify, and hold harmless Partner, its Affiliates, and their respective directors, officers, employees, agents and representatives (collectively, *"Partner Indemnitees"*), at Amgen's cost and expense, from and against any and all Losses arising out of any Third Party Claims brought against any Partner

Indemnitee to the extent such Losses result from: [*]. The indemnification obligations under this Section 13.2 (Indemnity by Amgen) exclude Losses to the extent they arise from [*] above in Section 13.1 (Indemnity by Partner).

13.3. Claim for Indemnification. Whenever any Third Party Claim or Loss arises for which a Partner Indemnitee or an Amgen Indemnitee (the *"Indemnified Party"*) may seek indemnification under this Article 13 (Indemnification and Insurance), the Indemnified Party will promptly notify the other Party (the *"Indemnifying Party"*) of the Third Party Claim or Loss; *provided*, that the failure by an Indemnified Party to give such notice will not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. The Indemnifying Party will have exclusive control of the defense and settlement of all Third Party Claims for which it is responsible for indemnification and will assume defense thereof at its own expense promptly upon notice of such Third Party Claim. In no event will the Indemnifying Party settle any Third Party Claim without the prior written consent of the Indemnified Party if such settlement (x) does not include a complete release from liability on such Third Party Claim, or (y) includes any admission of wrongdoing by the Indemnified Party or that any intellectual property or proprietary right of the Indemnified Party is invalid or unenforceable. The Indemnified Party will have the right to employ separate counsel at the Indemnifying Party's expense and to control its own defense of the applicable Third Party Claim if: (i) there are or may be legal defenses available to the Indemnified Party that are different from or additional to those available to the Indemnifying Party; or (ii) in the reasonable opinion of counsel to the Indemnified Party, a conflict or potential conflict exists between the Indemnified Party and Indemnifying Party that would make such separate representation advisable.

13.4. Defense of Third Party Claims. Except as otherwise provided in Section 13.3 (Claim for Indemnification), each Party (such Party referred to as the *"Defending Party"*) will have the sole right, but not the obligation, to defend against any Third Party Claims made against it with respect to its activities hereunder; *provided*, that any Third Party Claims relating to a nullification, declaratory judgment, opposition or revocation proceeding against any Product Intellectual Property will be governed by the provisions of Section 10.8 (Enforcement). Each Party will notify the other Party (the *"Assisting Party"*) as promptly as practicable if any such Third Party Claim is commenced or threatened against it, including any Infringement Claim. The Assisting Party will reasonably assist the Defending Party and cooperate in any such litigation at Defending Party's reasonable request. Without limiting the foregoing, the Defending Party will keep the Assisting Party advised of all material communications, actual and prospective filings or submissions regarding such action, and will provide the Assisting Party copies of and an opportunity to review and comment on any such communications, filings and submissions; *provided*, that each Party will have the right to redact from any information disclosed to the other hereunder any information relating to a product other than a Product or relating to the manufacture of a Product. The Defending Party will control the defense and settlement of Third Party Claims, with the costs thereof being included in General Costs, to the extent provided in Section 1.65.4. The Defending Party will not settle such Third Party Claim without the prior written consent of the other Party (such consent not to be unreasonably withheld), unless such settlement: [*]. In the event that a Third Party Claim is brought against both of the Parties (a *"Joint Claim"*), then the Parties will determine whether to defend against such Joint Claim, which of the Parties should be the Defending Party or whether the Parties should jointly control such defense and the strategy for such defense. In the case of an Infringement Claim, the coordination and cooperation set forth in this Section 13.4 (Defense of Third Party Claims) will be accomplished via the Patent Coordinators. This Section 13.4

(Defense of Third Party Claims) will not apply to employment or similar personnel-related claims.

13.5. Insurance. Each of the Parties will, at their own respective expense (and not subject to cost sharing hereunder) procure and maintain during the Term, insurance policies adequate to cover their obligations hereunder and consistent with the normal business practices of prudent pharmaceutical companies of similar size and scope (or reasonable self-insurance sufficient to provide materially the same level and type of protection). Such insurance will not create a limit to either Party's liability hereunder.

14. TERM AND TERMINATION

14.1. Term. This Agreement will become effective on the Effective Date and will continue during the Term.

14.2. Termination for Convenience.

14.2.1. Either Party will have the right to terminate this Agreement, either in whole or on a Product-by-Product basis, by providing the other Party with [*] prior written notice (or, after First Commercial Sale of a Product, [*] prior written notice with respect to such Product); *provided*, that a notice of termination with respect to a particular Product may only be provided after the Continued Development Meeting for such Product has occurred and a notice of termination with respect to the Agreement in whole may only be provided after the Continued Development Meetings for all Products have occurred.

14.2.2. [*].

14.3. Termination for Breach. In the event of a material breach of this Agreement, the non-breaching Party will have the right to terminate this Agreement, either in whole or (if such breach solely applies to a specific Product(s)) with respect to the applicable Product(s). The non-breaching Party may terminate this Agreement, whether in its entirety or on a Product-by-Product basis (as applicable), by written notice to the breaching Party, which notice will specify the nature of such breach in reasonable detail. Such termination will become effective on the date that is [*] days after the delivery thereof to the breaching Party (or, in the case of a failure to pay amounts due hereunder, [*] days) unless, during the [*] day (or [*] day) period after delivery of such notice to the breaching Party, the breaching Party has cured such breach to the reasonable satisfaction of the non-breaching Party. Notwithstanding the foregoing, in the event of a good faith dispute as to whether performance has been made by either Party pursuant to this Agreement, including any good faith dispute as to payments due under this Agreement, the relevant cure period with respect thereto will be tolled pending resolution of such dispute in accordance with the applicable provisions of this Agreement; *provided*, that if such dispute relates to payment, the cure period will only apply with respect to payment of disputed amounts, and not with respect to undisputed amounts.

14.4. Termination for Insolvency. Either Party will have the right to terminate this Agreement immediately upon written notice, if: (i) the other Party becomes insolvent; (ii) the other Party files a petition in bankruptcy, or if an involuntary petition in bankruptcy is filed against the other Party and such involuntary petition is not dismissed within seventy-five (75) days and the other Party (a) fails to assume this Agreement in any such bankruptcy proceeding within thirty (30) days after filing or (b) assumes and assigns this Agreement to a Third Party; or (iii) a receiver or guardian has been appointed for the other Party who is not discharged within seventy-five (75) days after appointment.

14.5. Termination for Challenge. Either Party will have the right to terminate this Agreement on a Product-by-Product basis by written notice to the other Party, if such other Party, its Affiliates or licensees bring or join any challenge to the validity or enforceability of (i) if Amgen is the challenging Party, any Partner Intellectual Property or any Program Intellectual Property, in each case as and to the extent such Partner Intellectual Property or Program Intellectual Property applies to the Product in the Collaboration Scope that is the subject of the termination notice; and (ii) if Partner is the challenging Party, any Amgen Intellectual Property (or any intellectual property corresponding to any such Amgen Intellectual Property in the Excluded Territory) or any Program Intellectual Property, in each case as and to the extent such Amgen Intellectual Property or Program Intellectual Property applies to a Product in the Collaboration Scope that is the subject of the termination notice. Notwithstanding the foregoing, nothing in this Section 14.5 (Termination for Challenge) will either: (a) prevent either Party from asserting any defense or counterclaim in an action for infringement of intellectual property, brought against such Party or its Affiliates, or any Third Party that such Party or any of its Affiliates is obligated to indemnify, or responding in any other manner to such an action for infringement; or (b) allow a Party to terminate this Agreement in the event the other Party asserts any such defense or counterclaim or otherwise responds in any such action for infringement.

14.6. Effects of Termination.

14.6.1. *Product by Product Termination*. Upon the termination of this Agreement by a Party with respect to one or more Products (each, a "*Terminated Product*"), the following will apply:

14.6.1.1. **Termination of Product**. Each Terminated Product will thereafter cease to be a Product for all purposes of this Agreement; and accordingly, for purposes of this Section 14.6 (Effects of Termination):

(i) "*Continuing Party*" means the Party that is not the Terminating Party;

(ii) "*Continuing Scope*" means with respect to a particular Terminated Product, the uses, countries and territories within the Collaboration Scope for such Terminated Product immediately prior to the Termination Effective Date;

(iii) "*Termination Effective Date*" means, with respect to a particular Terminated Product, the effective date of such termination with respect to such Terminated Product;

(iv) "*Terminated Product Intellectual Property Rights*" means (a) the Terminating Party's rights in and to the Program Intellectual Property and (b) (1) to the extent the Terminating Party is Amgen, the Amgen Terminated Product IP or (2) to the extent the Terminating Party is Partner, the Partner Terminated Product IP. For such purposes, "*Amgen Terminated Product IP*" and "*Partner Terminated Product IP*" mean, respectively, Amgen Intellectual Property and Partner Intellectual Property, but substituting for each reference to "Product" and "*Product Trademark*" therein, "*Terminated Product*" and "*Terminated Product Trademark,*" respectively; and

(v) "*Terminated Product Promotional Materials*" and "*Terminated Product Trademarks*" mean, respectively, Promotional Materials and Product Trademarks with respect to the Terminated Product (i.e., for such purposes, substituting in the definition of Promotional Materials and

Product Trademark a reference to "*Terminated Product*" for each reference to "*Product*").

(vi) "*Terminating Party*" means (a) the Party terminating the Agreement in the case of termination pursuant to Section 14.2 (Termination for Convenience); (b) the non-breaching Party in the case of termination pursuant to Section 14.3 (Termination for Breach); (c) the non-insolvent Party in the case of termination pursuant to Section 14.4 (Termination for Insolvency); and (d) the non-challenging Party in the case of termination pursuant to Section 14.5 (Termination for Challenge).

14.6.1.2. **Accrued Obligations**. Termination of this Agreement with respect to a Terminated Product will not release either Party from any liability (including any payment obligations) with respect to such Terminated Product that, at the time of such termination, has already accrued to the other Party or which is attributable to activities prior to such termination.

14.6.1.3. **Continuing Party's Rights**. The Continuing Party will have the sole right, as between the Parties, to develop, manufacture and commercialize the Terminated Product within the Continuing Scope. Accordingly, upon the Termination Effective Date for such Terminated Product, or such earlier time as specified below, and in each case subject to Section 14.6.1.5 (Amgen's Rights Outside Continuing Scope) below:

(i) Terminated Product Intellectual Property Rights. The Terminating Party will grant, and hereby grants, to the Continuing Party an exclusive, royalty-free license, including the right to grant and authorized sublicenses, under the Terminated Product Intellectual Property Rights to make, have made, use, sell, offer for sale and import the Terminated Product within the Continuing Scope. The Terminating Party will, subject to clause (vii) of this Section 14.6.1.3, immediately cease all of its development, manufacturing and commercialization activities for the Terminated Product.

(ii) Assignment of Trademarks. The Terminating Party will assign, and hereby assigns, to the Continuing Party all of the Terminating Party's rights, title and interest in and to the Terminated Product Trademarks for such Terminated Product (including any goodwill associated therewith), including all registrations therefore. Accordingly, the Terminating Party will cease all use of such Terminated Product Trademark.

(iii) Terminated Product Data. The Terminating Party will promptly transfer to the Continuing Party, at no cost, copies of all data, reports, records, materials and other Know-How in its possession or control that relate to the Terminated Product ("*Terminated Product Data*"), with such data to the extent they relate specifically to the Terminated Product becoming the Continuing Party's Confidential Information and shall cease to be the Terminating Party's Confidential Information. The Terminated Product Data will be provided in electronic form reasonably usable by the Continuing Party and, if reasonably necessary or useful in connection with the Continuing Party's (or its designee's) further commercialization, development or exploitation of the Terminated Product within the Continuing Scope, will include original hardcopies or duplicate copies thereof, as required.

(iv) Return of Confidential Information. The Terminating Party will promptly return to the Continuing Party, or destroy at the Continuing Party's request (and certify such destruction to the Continuing Party), all relevant records and materials in the Terminating Party's possession or control containing Confidential Information of the Continuing Party that is: (a) related to the Terminated Product within the Continuing Scope and (b) not reasonably necessary for the Terminating Party to exercise any remaining rights or fulfill any remaining obligations it has under this Agreement after such termination; *provided*, that the Terminating Party (1) may keep one copy of such Confidential Information of the Terminating Party for archival purposes or as otherwise required under Applicable Law; and (2) ensures such copies are Segregated from any Distracting Program).

(v) Return of Samples and Materials. The Terminating Party will promptly transfer to the Continuing Party, or destroy at the Continuing Party's request (and certify such destruction to the Continuing Party), all samples, Terminated Product Promotional Materials, sales training materials and any other documents, or materials primarily intended for use in commercialization of the Terminated Product within the Continuing Scope.

(vi) Assignment of Regulatory Filings and Approvals; Copyrights; Domain Names. The Terminating Party will, at its own expense (other than with respect to any fee payable to the relevant Governmental Authority in connection with the relevant assignment, which will be borne by the Continuing Party), assign, and hereby assigns, to the Continuing Party all Regulatory Filings and Regulatory Approvals related to the Terminated Product within the Continuing Scope, and all copyrights, copyright registrations, domain names and domain name registrations related to the Terminated Product (or to the Terminated Product Promotional Materials) within the Continuing Scope. The Terminating Party will promptly submit any necessary notices to Governmental Authorities to effect such assignments. If Applicable Laws prevent or delay the transfer of ownership of any such Regulatory Filing or Regulatory Approval to the Continuing Party, the Terminating Party will grant, and does hereby grant, to the Continuing Party an exclusive and irrevocable right of access and reference to such Regulatory Filing and Regulatory Approvals for purposes of developing and commercializing the Terminated Product within the Continuing Scope, and will cooperate fully to make the benefits of such Regulatory Filings and Regulatory Approvals available to the Continuing Party or its designee(s) for purposes within the Continuing Scope for such Terminated Product. Promptly upon request following the notice of termination, the Terminating Party will provide to the Continuing Party copies of all such Regulatory Filings and Regulatory Approvals. For purposes of this Section 14.6.1 (Product by Product Termination), references to Product in the defined terms Regulatory Filings and Regulatory Approvals shall be replaced with references to Terminated Product.

(vii) Transition. During the applicable notice period prior to the Termination Effective Date, the Terminating Party will continue to meet its obligations to develop, manufacture, and commercialize Products within the Collaboration Scope, in accordance with the applicable

Development Plan, Brand Plan and Country Plan and this Agreement and bear its proportionate share of expenses with respect thereto, unless otherwise agreed by the Parties or specified in this Section 14.6 (Effects of Termination). Upon request by the Continuing Party, the Terminating Party will undertake reasonable efforts to effect a smooth and orderly transition of all development, manufacturing and commercial activities and responsibilities under this Agreement with respect to the Terminated Product to the Continuing Party (or, in the case of manufacturing activities, to a mutually agreed upon Third Party contract manufacturer), as soon as reasonably possible, to enable the Continuing Party to continue the development, manufacturing and commercialization of the Terminated Product in the Continuing Scope. Without limiting the foregoing:

A. Continued Supply. The Terminating Party will transfer to the Continuing Party all quantities of the Terminated Product in its possession for which the manufacturing costs were shared by the Parties under Article 7 (Profit/Expense Sharing). In addition, the Terminating Party will, at the Continuing Party's cost and expense, reasonably cooperate, as requested by the Continuing Party, to ensure uninterrupted supply of the Terminated Product. To the extent the Terminating Party was responsible for manufacturing the Terminated Product as of the Termination Effective Date, then the Terminating Party will continue to provide for manufacturing of such Terminated Product for the Continuing Party, at the fully-burdened manufacturing cost therefore, from the date of notice of such termination with respect to such Terminated Product, until the sooner to occur of such time as the Continuing Party is able, using Commercially Reasonable Efforts to do so, to secure an acceptable alternative manufacturing source from which sufficient quantities of Terminated Product may be procured or [*] months from the Termination Effective Date.

B. Contracts. If the Terminating Party is, as of the Termination Effective Date, party to any Third Party contracts that pertain solely to the Continuing Scope with respect to a Terminated Product, then it will provide the Continuing Party notice and (to the extent permitted to do so) copies thereof; and the Terminating Party will assign to the Continuing Party any such contracts requested by the Continuing Party, to the extent it has the right under such contract(s) to do so (and will use Commercially Reasonable Efforts to obtain any required consents).

14.6.1.4. **Distracting Products**. Notwithstanding anything herein to the contrary, if Amgen is terminating this Agreement pursuant to Section 14.2 (Termination for Convenience), Article 9 (Distracting Products) will continue to apply with respect to the Terminated Product for [*] thereafter. In addition, for any termination hereunder, with respect to Article 9 (Distracting Product), each reference to "*Product*" or "*Product Target*" in the definitions of Distracting Product and Distracting Target will be deemed to a reference to include the Terminated Product and the Product Target corresponding to such Terminated Product.

14.6.1.5. **Amgen's Rights outside Continuing Scope**. Notwithstanding the foregoing provisions of this Section 14.6.1 (Product by Product Termination):

(i) Terminated Product Intellectual Property Rights. Partner will grant, and hereby grants (effective upon the Termination Effective Date), to Amgen an [*], royalty-free, [*] license, including the right to grant and authorize sublicenses, under the Partner Terminated Product IP and Partner's rights in and to the Program Intellectual Property to use, sell, offer for sale and import Terminated Products in the Excluded Territory, and to make and have made the Terminated Product for use and sale in the Excluded Territory, and the last sentence of Section 2.2 (Ex-Territory Activities) shall continue to apply with respect to the Terminated Product. In addition, Amgen will retain, and not assign to Partner, Amgen's right, title or interest in the Terminated Product Trademarks in the Excluded Territory.

(ii) Terminated Product Data. If Amgen is the Terminating Party with respect to a Terminated Product, upon request by Amgen from time to time, Partner will promptly provide to Amgen at no cost, copies of Terminated Product Data then in Partner's possession or control that relate to such Terminated Product, for use in the Excluded Territory in relation to the Terminated Product. Such Terminated Product Data will be provided in electronic form reasonably usable by Amgen and, if reasonably necessary or useful in connection with Amgen's (or its designee's) further commercialization, development or exploitation of Terminated Products in the Excluded Territory, will include original hardcopies or duplicate copies thereof, as required.

(iii) Regulatory Filings; Regulatory Approvals. Partner will grant, and does hereby grant (effective upon the Termination Effective Date), to Amgen an exclusive and irrevocable right of access and reference to any and all Regulatory Filings and Regulatory Approvals for the Terminated Product for purposes in the Excluded Territory, and will cooperate fully to make the benefits of such Regulatory Filings and Regulatory Approvals available to Amgen or its designee(s) for purposes in the Excluded Territory. Promptly upon request by Amgen from time to time, Partner will provide to Amgen copies of all Regulatory Filings and Regulatory Approvals (and all underlying data) with respect to such Terminated Product held by or on behalf of Partner.

(iv) Excluded Territory Agreements. In the event that Amgen is the Terminating Party for either AMG827 or AMG557, Partner, at the request of Amgen, will enter into good faith negotiations for the purpose of establishing direct communications and engagement between Partner and (i) Kirin-Amgen, Inc., in the case of AMG827, and (ii) Takeda Pharmaceutical Company Limited, in the case of AMG557, as necessary to fulfill Amgen's obligations under the applicable Excluded Territory Agreement.

14.6.1.6. **Royalty Payment**. On a Terminated Product-by-Terminated Product basis, other than with respect to the AMG157 Termination Event, the Continuing Party will pay to the Terminating Party a tiered royalty on aggregate Terminated Product Net Revenues for such Terminated Product by the Continuing Party and its Affiliates (but not by its licensees or sublicensees) as follows:

Calendar Year Net Revenues for Terminated Product	Royalty Rate
Less than or equal to [*]	[*]
Greater than [*] and less than or equal to [*]	[*]
Greater than [*]	[*]

Additionally, [*], the Continuing Party will pay to the Terminating Party [*] of any and all Sublicensing Revenues received by the Continuing Party and/or its Affiliates.

Additionally, if Partner is the Continuing Party, Partner will pay to Amgen an additional royalty equal to the applicable Terminated Product Inventorship Margin on Terminated Product Net Revenues by Partner, its Affiliates and sublicensees.

Such royalty will be payable quarterly within thirty (30) days of the end of the calendar quarter for which such royalties are owed. Each royalty payment will be accompanied by a report setting forth Partner's calculation of Net Revenues and royalties owed for the applicable quarter. For such purposes, "*Terminated Product Net Revenues*" means "*Net Revenues,*" and "*Terminated Product Inventorship Margin*" will mean the "*Inventorship Margin,*" but for such purposes substituting in such definitions (including in each definition referenced in such definitions) a reference to "*Terminated Product*" for each reference to "*Product;*" and Sections 7.4 (Calculation of Net Revenues) and 8.3 (Currency) through 8.7 (Late Payment) (inclusive) will apply with respect to such royalty payments, mutatis mutandis.

14.6.2. *Termination of Agreement in Entirety.* In the event (i) this Agreement is terminated by Partner in its entirety under Section 14.2 (Termination for Convenience) or is terminated in its entirety under Sections 14.3 (Termination for Breach) through 14.5 (Termination for Challenge) (inclusive), or (ii) if as of the Termination Effective Date with respect to a Terminated Product, there are no other Products then being developed or commercialized under this Agreement, and Partner is not then developing or commercializing a Terminated Product as the Continuing Party under Section 14.6.1 (Product by Product Termination) above; then in either such case, the Agreement will terminate in whole, and all provisions of this Agreement will terminate as of the effective date of such termination, except as expressly set forth in Sections 14.6.1 (Product by Product Termination) and 14.6.3 (Survival) below.

14.6.3. *Survival.* Articles 1 (Definitions), 7 (Profit/Expense Sharing) (with respect to periods prior to termination), 8 (Payments) (with respect to periods prior to termination), 9 (Distracting Products) (only with respect to such continuing periods as expressly referenced in such Article), 13 (Indemnification and Insurance) (with respect to periods prior to termination), and 15 (Miscellaneous) and Sections 2.2 (Ex-Territory Activities), 3.4 (Product Complaints, Recalls and Returns), 5.8 (Detailing Reports and Audit Rights) (with respect to periods prior

to termination), 5.9 (Competing Products) (with respect to periods prior to termination), 10.1 (Invention Ownership), 10.3 (Joint Ownership), 10.4 (License Grant by Amgen) (only with respect to the transition period referenced in clause (vii) of Section 14.6.1.3 (Transition)), 10.5 (License Grant by Partner), 10.8 (Enforcement) (with respect to enforcement against activities that took place prior to or termination), 10.9 (Patent Term Extensions) (with respect to periods prior to termination), 10.10.3 (Housemark Licenses) (with respect to the transition period referenced in clause (vii) of Section 14.6.1.3 (Transition) and the sell-off period referenced therein), 11.1 (Confidentiality; Exceptions), 11.2 (Authorized Disclosure), 11.3 (Confidential Treatment of Terms and Conditions), 11.5 (Prior Agreement), and this 14.6 (Effects of Termination) (with all Products deemed Terminated Products and Amgen being the Continuing Party for all Terminated Products) will survive termination of this Agreement for any reason. Except as otherwise provided in this Section 14.6 (Effects of Termination), all rights and obligations of the Parties under this Agreement will terminate upon termination of this Agreement for any reason.

14.6.4. *No Limitation of Rights.* The rights provided in this Article 14 (Term and Termination) will be in addition and without prejudice to any other rights which the Parties may have with respect to any default or breach of the provisions of this Agreement. Termination is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies at equity or law will remain available to the Parties except as expressly agreed otherwise herein.

15. MISCELLANEOUS

14.1. Affiliates. Each Party will have the right to exercise its rights and perform its obligations hereunder through its Affiliates (including by licensing rights hereunder where such rights are held in the name of any such Affiliate); *provided*, that such Party will be responsible for its Affiliates' performance hereunder.

14.2. Assignment. Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred (whether by operation of Applicable Law, general succession or otherwise) by either Party without the prior written consent of the other Party; *provided*, that either Party may assign this Agreement, or rights and obligations hereunder, without prior written consent to any Affiliate (as long as such entity remains an Affiliate of the relevant Party), or in connection with the transfer or sale of all or substantially all of the business to which this Agreement relates. Any assignment not in accordance with this Agreement will be void ab initio. Subject to the foregoing, the rights and obligations of the Parties under this Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.

14.3. Choice of Law; Jurisdiction. This Agreement will be governed by, and enforced and construed in accordance with, the laws of the State of New York without regard to its conflicts of law provisions, except as to any issue which depends upon the validity, scope or enforceability of any Patent, which issue will be determined in accordance with the laws of the country in which such patent was issued. Each of the Parties hereby irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the state and federal courts of the State of New York for any matter arising out of or relating to this Agreement and the transactions contemplated hereby, and agrees not to commence any litigation relating thereto except in such courts. Each of the Parties hereby irrevocably and unconditionally waives any objection to the laying of venue of any matter arising out of this Agreement or the transactions contemplated hereby in the state and federal courts of the State of New York and hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such matter brought in any such court has been brought in an inconvenient forum. The

Parties agree that a final judgment in any such matter will be conclusive and may be enforced in other jurisdictions by suits on the judgment or in any other manner provided by law. Any proceeding brought by either Party under this Agreement will be exclusively conducted in the English language. The United Nations Convention for the International Sale of Goods will not apply to the transactions contemplated herein.

14.4. Construction. The definitions of the terms herein will apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation". The word "or" is used in the inclusive sense (and/or). The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction will be applied in the interpretation hereof. Unless the context requires otherwise: (i) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein); (ii) any reference to any Applicable Law herein will be construed as referring to such Applicable Law as from time to time enacted, repealed or amended; (iii) any reference herein to any person will be construed to include the person's permitted successors and assigns; (iv) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof; and (v) all references herein to Articles, Sections, or Schedules, unless otherwise specifically provided, will be construed to refer to Articles, Sections or Schedules of this Agreement. This Agreement has been executed in English, and the English version of this Agreement will control.

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

14.6. Entire Agreement. This Agreement, including the attached Schedules, constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior or contemporaneous negotiations, representations, agreements and understandings regarding the same.

14.7. Force Majeure. Neither Party will be liable for delay or failure in the performance of any of its obligations hereunder (other than the payment of money) to the extent such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, pandemics, earthquakes, labor strikes, acts of war, terrorism or civil unrest ("*Force Majeure*"); *provided*, that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect); and *provided*, further that the affected Party uses its Commercially Reasonable Efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and will continue performance with reasonable dispatch whenever such causes are removed.

14.8. Further Assurances. Each Party agrees to do and perform all such further acts and things and will execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

14.9. Headings. Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.

14.10. No Set-Off. Except as expressly set forth in Section 7.2.9 (True-Up), Section 8.6.1 (Withholding) or Section 8.6.2 (Indirect Taxes), no Party will have the right to deduct from amounts otherwise payable hereunder any amounts payable to such Party (or its Affiliates) from the other Party (or its Affiliates), whether pursuant to this Agreement or otherwise.

14.11. Notices. Any notice required or permitted to be given by this Agreement will be in writing, in English, and will be delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by registered or certified mail addressed as set forth below unless changed by notice so given:

If to Amgen: Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799
Attention: Corporate Secretary
Telephone: 805-447-1000
Facsimile: [*]

If to Partner: AstraZeneca Collaboration Ventures, LLC
One MedImmune Way
Gaithersburg, Maryland 20878
Attention: President
Telephone: [*]
Facsimile: [*]

With a copy to the Secretary of AstraZeneca Collaboration Ventures, LLC at the above address.

Any such notice will be deemed given on the date delivered. A Party may add, delete (so long as at least one person is remaining), or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 15.11 (Notices).

14.12. Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. The Parties will operate their own businesses separately and independently and they will hold themselves out as, act as, and constitute independent contractors in all respects and not as principal and agent, partners or joint venturers. Neither party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

14.13. Severability. To the fullest extent permitted by Applicable Law, the Parties waive any provision of Applicable Law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect or to any extent, then in such respect and to such extent such provision will be given no effect by the Parties and will not form part of this Agreement. To the fullest extent permitted by Applicable Law, all other provisions of this Agreement will remain in full force and effect and the Parties will use their commercially reasonable efforts to negotiate a provision in replacement

of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the Parties.

14.14. Third Party Beneficiaries. Except as expressly provided with respect to Amgen Indemnitees or Partner Indemnities in Article 13 (Indemnification and Insurance), there are no Third Party beneficiaries intended hereunder and no Third Party will have any right or obligation hereunder.

14.15. Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder will not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof will not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any other occasion. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement will be valid or effective unless in writing and signed by all Parties hereto.

14.16. [*].

****

(Signature page follows)

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

ASTRAZENECA COLLABORATION VENTURES, LLC

By: /s/ Peter Greenleaf

Name: Peter Greenleaf

Title: President

AMGEN INC.

By: /s/ David J. Scott

Name: David J. Scott

Title: SVP, General Counsel & Secretary

ASTRAZENECA PHARMACEUTICALS LP

By: /s/ Ann Booth Barbarin

Name: Ann Booth Barbarin

Title: Assistant Secretary

Schedule
AMG827 Territory

Column 1	**Column 2**	**Column 3**
European Countries	***Central and South American Countries***	***African and Middle East Countries***
Albania	Antigua and Barbuda	Algeria
Andorra	Argentina	Angola
Armenia	Bahamas	Bahrain
Austria	Barbados	Angola
Azerbaijan	Belize	Benin
Belarus	Bolivia	Botswana
Belgium	Brazil	Burkina Faso
Bosnia-Herzg.	Chile	Cameroon
Bulgaria	Colombia	Central African Republic
Croatia	Costa Rica	Congo (Democratic Republic of)
Czech Republic	Cuba	Congo (Republic of the)
Denmark	Dominica	Cote D'Ivoire/Ivory Coast
Estonia	Dominican Republic	Cyprus
Finland	Ecuador	Djibouti
France	El Salvador	Egypt
Georgia	French Guiana	Eritrea
Germany	Grenada	Ethiopia
Greece	Guatemala	Gabon
Hungary	Guyana	Gambia
Iceland	Honduras	Ghana
Ireland	Jamaica	Gibraltar
Italy	Nicaragua	Greenland
Latvia	Panama	Iran
Lithuania	Paraguay	Iraq
Liechtenstein	Peru	Israel
Luxembourg	Saint Kitts and Nevis	Jordan
Macedonia	Saint Lucia	Kazakhstan
Malta	Saint Vincent and the Grenadines	Kenya
Moldova	Suriname	Kuwait
Monaco	Trinidad and Tobago	Kyrgyzstan
Netherlands	Uruguay	Lesotho
Norway	Venezuela	Lebanon
Poland		Liberia
Portugal		Libya
Romania		Madagascar
Russia		Malawi
San Marino		Mauritania
Serbia and Montenegro		Mauritius

Column 1	Column 2	Column 3
Slovakia		Morocco
Slovenia		Mozambique
Sweden		Namibia
Switzerland		Niger
Spain		Nigeria
		Oman
		Qatar
		Rwanda
		Saudi Arabia
		Senegal
		Seychelles
		Sierra Leone
		Somalia
		South Africa
		Sudan
		Swaziland
		Syria
		Tajikistan
		Tanzania
		Tunisia
		Turkey
		Turkmenistan
		Uganda
		United Arab Emirates
		Uzbekistan
		Yemen
		Zambia
		Zimbabwe

Schedule
Amgen Distribution Countries

[*]	[*]	[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]
[*]	[*]		
	[*]	[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]
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[*]		[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]
[*]	[*]	[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]
[*]	[*]		

Schedule
Commercial Allocation

AMG827-

Respiratory-

Partner will have the sole right to Detail Products in the Respiratory market in the Collaboration Territory.

Rheumatology-

Amgen will have the sole right to Detail Products in the Rheumatology market in North America, Europe, Australia and New Zealand.

For the Rheumatology market in all other countries in the Collaboration Territory, the Parties shall enter into discussions regarding the allocation of Details beginning [*] prior to the anticipated first commercial launch of AMG827 for a Rheumatology indication. The JSC shall agree upon the allocation of Details between the Parties taking into account all relevant factors [*]; *provided*, that if the JSC is unable to agree upon the allocation of Details in any country, then such matter shall be escalated to the CRC; *provided*, *further*, that if the CRC is unable to agree upon the allocation of Details in any country, [*]. To the extent less than one hundred percent (100%) of the Details in any such country have been allocated to the Parties, the Parties shall [*]. If the Parties in the aggregate elect to Detail in excess of one hundred percent (100%) of the Details in any such country, then each Party will be entitled to only [*].

Dermatology-

Amgen will have the sole right to Detail Products in the Dermatology market in North America.

For the Dermatology market in all other countries in the Collaboration Territory, Partner will have the sole right to Detail Products, provided, that, to the extent Amgen has or develops a commercial capability to Detail Products consistent with the Brand Plan in the Dermatology market in any such country, so that in such country Amgen would have the capability to provide [*] percent ([*]%) of the Details in that country, Amgen will have the right to provide [*] percent ([*]%) of such Details in such country, provided that Amgen shall not have the right to provide Details in countries which collectively represent in excess of [*] percent ([*]%) of [*] of all countries in the Collaboration Territory [*]. If Amgen determines that it wishes to build a commercial capability in a country (without necessarily having sufficient capability to provide [*] percent ([*]%) of the Details in that country) the Parties will discuss in good faith allocation of Details in such country to determine what is in the best interests of the Product in that country according to the then current Brand Plan.

Additional Indications-
For all market segments other than Respiratory, Rheumatology and Dermatology, the Parties shall enter into discussions regarding the allocation of Details beginning [*] prior to the anticipated first commercial launch of AMG827 for such market segment. The JSC shall agree upon the allocation of Details between the Parties taking into account all relevant factors [*]; *provided*, that if the JSC is unable to agree upon the allocation of Details in any country, then such matter shall be escalated to the CRC; *provided, further,* that if the CRC is unable to agree upon the allocation of Details in any country, [*]. To the extent less than one hundred percent (100%) of the Details in any such country have been allocated to the Parties, the Parties shall [*]. If the Parties in the aggregate elect to Detail in excess of one hundred percent (100%) of the Details in any such country, then each Party will be entitled to only [*].

Definitions-

"Dermatology" means the branch of medicine dealing with the skin and its diseases or disorders, including psoriasis and atopic dermatitis.

"Respiratory" means the branch of medicine dealing with inflammatory respiratory diseases or disorders and obstructive respiratory diseases or disorders, including asthma and chronic obstructive pulmonary disease (COPD).

"Rheumatology" means the branch of medicine dealing with rheumatic diseases or disorders, including rheumatoid arthritis, systemic lupus erythematosus (SCE), psoriatic arthritis, and ankylosing spondylitis.

All Other Products-

For all other Products, the Parties shall, on a market segment basis, enter into discussions regarding the allocation of Details for a Product beginning [*] prior to the anticipated first commercial launch of such Product for such market segment. The JSC shall agree upon the allocation of Details between for such Product in such market segment the Parties taking into account all relevant factors ([*]); *provided*, that if the JSC is unable to agree upon the allocation of Details in any country, then such matter shall be escalated to the CRC; *provided, further,* that if the CRC is unable to agree upon the allocation of Details in any country, [*]. To the extent less than one hundred percent (100%) of the Details in any such country have been allocated to the Parties, the Parties shall [*]. If the Parties in the aggregate elect to Detail in excess of one hundred percent (100%) of the Details in any such country, then each Party will be entitled to only [*].

Schedule
Completed Clinical Trials

AMG 139
Ph 1a FIH single ascending dose study (20080767)

AMG 157
Ph 1a FIH single ascending dose study (20070620)
Ph 1b multiple ascending dose study (20080390)

AMG 557
Ph 1a FIH single ascending dose study in SLE subjects (2006132)
Ph 1b MAD in SLE subjects (2007169)

AMG 827
Ph1 device preference study in HV (20110106)
Ph 1a FIH single ascending dose study (20060279)
Ph 1b multiple ascending dose study in RA (20070264)
Ph 2 multiple dose, dose ranging study in RA (20090061)
Ph 2 open label extension study in RA (20090402)
Ph 2 multiple dose, dose ranging study in psoriasis (20090062)
Ph 2 multiple dose, dose ranging study in CD (20090072)
Ph 2 open label extension study in CD (201000008)
Ph 2 multiple dose, dose ranging study in asthma (20090203)

Schedule
[*] Designated Endpoints [*]

All of the following criteria must be met for a go decision to commence a [*] Trial.

- [*]: A statistically significant [*] and clinically significant ([*]) change in [*] from [*] at [*] for [*] and the [*] performs similarly to or better than the [*].

- [*]: A trend in [*] of [*] from [*] for [*] and the [*]. [*] are defined as [*] leading to [*] for [*]. The [*] in [*] will be [*] with the [*]. If the [*], then [*] and the [*].

- [*]: There are no [*] that [*].

Schedule
Development/Commercial Lead

Amgen	Partner
AMG827	AMG139
AMG557	AMG157
	AMG181

[*] -

1 Specifically with regard to AMG827 at the global level, the Parties will work closely through the JPT on the commercial strategy for the Respiratory market for AMG827 with Amgen taking the primary responsibility for [*].

2 [*].

3 The Parties will cooperate to ensure that [*] is made available to the JPT at both the global and regional level.

4 This arrangement will be noted in the press release and other approved communications as “[*]” or with words of similar import.

Schedule
Distracting Product

Product	Product Target	Distracting Target*
AMG 139	[*]	[*]
AMG 157	[*]	[*]
AMG 181	[*]	[*]
AMG 557	[*]	[*]
AMG 827	[*]	[*]

*Distracting Target includes (i) any [*]; (ii) any [*]; (iii) any [*]; (iv) any [*]; and (v) any [*]. For avoidance of doubt, the Distracting Product Schedule lists [*].

Schedule
Invoice

Amgen Inc.
Invoice Template
2nd Quarter 2012 - Example Period

	A	B	C = A + B	D	E	F = D + E	G = A - F	
	Total Quarterly Spend*			Amgen's Share of...**			Amount due	
Product	Amgen	Partner	Total	Amgen's Spend	Partner's Spend	Total Spend	(From)/To Amgen	
AMG 139	$ -	$ -	$ -	$ -	$ -	$ -	$ -	
AMG 157	$ -	$ -	$ -	$ -	$ -	$ -	$ -	
AMG 181	$ -	$ -	$ -	$ -	$ -	$ -	$ -	
AMG 557	$ -	$ -	$ -	$ -	$ -	$ -	$ -	
AMG 827	$ -	$ -	$ -	$ -	$ -	$ -	$ -	
Total	$ -	$ -	$ -	$ -	$ -	$ -	$ -	***<<< Amount Billed or Reimbursed to Partner***

Notes
* Total spend derived from Column K on Page 2 and Column C on Page 3
** Amgen's Share of Total Spend derived from Column L on Page 2 and Column D on Page 3

Amgen Inc.
Invoice Template
2nd Quarter 2012 - Example Period

Step 1: Calculation of Total *AMGEN* Cost less Amount Reimbursed by 3rd Party

		A	B	C = A + B	D = C x 35%	E = C - D	F	G	H = F + G	I = H x 70%	J = H - I	K = C + H	L = D + I	M = E + J
		Total Costs Excluding AMG827 Ph2b Asthma Study					Costs for AMG827 Ph2b Asthma Study					Total Amgen Costs		
		Gross Spend			Amgen Share	Partner Share	Gross Spend			Amgen Share	Partner Share			
Function	Product	OSE	FTE	Total	35%	65%	OSE	FTE	Total	70%	30%	Total	Amgen Share	Partner Share
R&D	AMG 139			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 157			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 181			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 557			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 827			$ -	$ -	$ -			$ -	$ -	$ -	$ -	$ -	$ -
	Sub-Total R&D	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**
Operations	AMG 139			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 157			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 181			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 557			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 827			$ -	$ -	$ -			$ -	$ -	$ -	$ -	$ -	$ -
	Sub-Total Ops	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**
Commercial	AMG 139			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 157			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 181			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 557			$ -	$ -	$ -						$ -	$ -	$ -
	AMG 827			$ -	$ -	$ -						$ -	$ -	$ -
	Sub-Total Comm'l	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**
Total	AMG 139	$ -	$ -	$ -	$ -	$ -						$ -	$ -	$ -
	AMG 157	$ -	$ -	$ -	$ -	$ -						$ -	$ -	$ -
	AMG 181	$ -	$ -	$ -	$ -	$ -						$ -	$ -	$ -
	AMG 557	$ -	$ -	$ -	$ -	$ -						$ -	$ -	$ -
	AMG 827	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	Grand Total	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**

Notes
1. Page reflects Total Costs Incurred by/Reimbursed to ***AMGEN only***
2. The values in the "Total" Row will be used for the following purposes on Page 1
- Determine the combined (Amgen + Partner) Total Cost of all programs in a quarter
- Deduct the actual expenses incurred/paid by Amgen from Amgen's share of quarterly expenses

Amgen Inc.
Invoice Template
2nd Quarter 2012 - Example Period

Costs Incurred by Partner

		A	B	C = B+A	D = 35% x C	E = C-D
Function	**Product**	**FTE**	**OSE**	**Total Costs**	**Amgen Share 35%**	**Partner Share 65%**
R&D	AMG 139			**$ -**	$ -	$ -
	AMG 157			**$ -**	$ -	$ -
	AMG 181			**$ -**	$ -	$ -
	AMG 557			**$ -**	$ -	$ -
	AMG 827			**$ -**	$ -	$ -
	Total	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**
Operations	AMG 139			**$ -**	$ -	$ -
	AMG 157			**$ -**	$ -	$ -
	AMG 181			**$ -**	$ -	$ -
	AMG 557			**$ -**	$ -	$ -
	AMG 827			**$ -**	$ -	$ -
	Total	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**
Commercial	AMG 139			**$ -**	$ -	$ -
	AMG 157			**$ -**	$ -	$ -
	AMG 181			**$ -**	$ -	$ -
	AMG 557			**$ -**	$ -	$ -
	AMG 827			**$ -**	$ -	$ -
	Total	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**
Total	AMG 139	$ -	$ -	**$ -**	$ -	$ -
	AMG 157	$ -	$ -	**$ -**	$ -	$ -
	AMG 181	$ -	$ -	**$ -**	$ -	$ -
	AMG 557	$ -	$ -	**$ -**	$ -	$ -
	AMG 827	$ -	$ -	**$ -**	$ -	$ -
	Total	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**

Notes

1. On this tab, Amgen will capture the quarterly spend incurred by partner for aggregation purposes
2. Table above is a placeholder/stand-in which will be replaced by the quarterly actual cost summary provided by partner
3. The values in the “Total” Row will be used for the following purposes on Page 1
- Determine the combined (Amgen + Partner) Total Cost of all programs in a quarter
- Deduct the actual expenses incurred/paid by partner from the partner’s share of quarterly expenses

Schedule
Press Release

News Release

AMGEN AND ASTRAZENECA ANNOUNCE COLLABORATION TO JOINTLY DEVELOP AND COMMERCIALIZE CLINICAL-STAGE INFLAMMATION PORTFOLIO

Collaboration Comprises Five Monoclonal Antibodies

Brodalumab (AMG 827) Phase 3 Trial Planned in 2012

THOUSAND OAKS, Calif. and LONDON (April 2, 2012)—Amgen (NASDAQ:AMGN) and AstraZeneca Plc, today announced an agreement to jointly develop and commercialize five monoclonal antibodies from Amgen's clinical inflammation portfolio (AMG 139, AMG 157, AMG 181, AMG 557 and brodalumab (AMG 827)).

The companies believe all the molecules have novel profiles and offer the potential to deliver important treatments across multiple indications in inflammatory diseases. The collaboration will provide Amgen with additional resources to optimally progress its portfolio, and Amgen will benefit from the strong respiratory, inflammation and asthma development expertise of MedImmune, AstraZeneca's biologics arm. The collaboration will also capitalize on AstraZeneca's global commercial reach in respiratory and gastrointestinal diseases. The agreement does not include certain territories previously partnered by Amgen for brodalumab with Kyowa Hakko Kirin and AMG 557 with Takeda.

Under the terms of the agreement, AstraZeneca will make a one-time $50 million upfront payment and the companies will share both costs and profits. Based on current plans, approximately 65 percent of costs for the 2012-2014 period will be funded by AstraZeneca. Thereafter, the companies will split costs equally. Amgen will book sales globally and will retain a low single-digit royalty for brodalumab and a mid single-digit royalty for the rest of the portfolio, after which the companies will share profits equally.

AstraZeneca will lead the development and commercialization strategy of AMG 139, AMG 157 and AMG 181, while Amgen will lead the development and commercialization strategy of brodalumab and AMG 557. Each development and commercialization lead will be under the oversight of joint governing bodies. For brodalumab, commercial promotion will be split. Amgen will promote in dermatology indications in the United States (U.S.) and Canada, and in rheumatology indications in U.S., Canada and Europe. AstraZeneca will promote in respiratory and, initially, in dermatology indications of brodalumab across all territories outside the U.S., Canada and those markets where Amgen has existing partnerships. Allocation of promotional rights for other territories, indications and molecules will be agreed later between the companies.

"We are delighted to join forces with Amgen in developing and commercializing these novel clinical-stage assets that add value to our pipeline and build on our expertise in biologics. This creative collaboration will make the most of both companies' respective capabilities, including AstraZeneca's extensive global reach, to help bring these potentially innovative treatment options for a variety of respiratory and inflammatory diseases to patients around the world," said David Brennan, Chief Executive Officer, AstraZeneca.

"We are very excited at the prospect of collaborating with a well-respected organization like AstraZeneca to advance our inflammation pipeline," said Kevin Sharer, Chairman and CEO at Amgen. "We believe this collaboration has the potential to bring more therapies to patients sooner, across more geographic areas. We are impressed with AstraZeneca's

extensive experience in developing and launching products in the respiratory and gastroenterology areas, and believe this collaboration is an opportunity to work with a partner that has leading regulatory and commercial expertise in inflammation indications."

-ENDS-

NOTES TO EDITORS

About the inflammation portfolio included in the agreement

Under the agreement, the companies will jointly develop and commercialize the following five assets from Amgen's clinical-stage portfolio:

- **Brodalumab (AMG 827)** is a human monoclonal antibody that binds to and blocks signaling via the IL-17 receptor. Brodalumab is being investigated for psoriasis (completed Phase 2 and planned Phase 3), psoriatic arthritis (Phase 2) and asthma (Phase 2).

- **AMG 139** is a human monoclonal antibody. AMG 139 is being investigated in Phase 1b for Crohn's disease.

- **AMG 181** is a human monoclonal antibody. AMG 181 is being investigated in Phase 1a and Phase 1b for ulcerative colitis and Crohn's disease.

- **AMG 557** is a human monoclonal antibody that binds to B7-related protein 1 (B7RP-1). AMG 557 is being investigated in Phase 1b for autoimmune diseases such as systemic lupus erythematosus.

- **AMG 157** is a human monoclonal antibody that blocks interaction of thymic stromal lymphopoietin (TSLP) with the TSLP receptor. AMG 157 is being investigated in Phase 1b for asthma.

About Amgen

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com. Follow us on www.twitter.com/amgen.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com.

Amgen Forward Looking Statements

This news release contains forward-looking statements that are based on Amgen's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-

looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and most recent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to Amgen's business. Unless otherwise noted, Amgen is providing this information as of April 2, 2012 and expressly disclaims any duty to update information contained in this news release.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Amgen develops product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with Amgen's products after they are on the market. Amgen's business may be impacted by government investigations, litigation and products liability claims. Amgen depends on third parties for a significant portion of its manufacturing capacity for the supply of certain of its current and future products and limits on supply may constrain sales of certain of its current products and product candidate development.

In addition, sales of Amgen's products are affected by the reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of Amgen's products. In addition, Amgen competes with other companies with respect to some of its marketed products as well as for the discovery and development of new products. Amgen believes that some of its newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen's products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with its products. In addition, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors and there can be no guarantee of Amgen's ability to obtain or maintain patent protection for its products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of its existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of its products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's business and results of operations.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Only the FDA can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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Schedule
Products

Product
AMG 139
AMG 157
AMG 181
AMG 557
AMG 827

Schedule
Profit (Loss) Example

This schedule provides examples of the calculation of the Inventorship Margin and the calculation of the Profit (Loss) True-Up pursuant to Section 7.2.8 (Calculation of Profit (or Loss)).

I. **Inventorship Margin**. Assume for purposes of this example that Net Revenues are as follows:

	Q1 2017	Q2 2017	Q3 2017	Q4 2017
Net Revenues (excluding AMG827):	[*]	[*]	[*]	[*]
Net Revenues (AMG827 only):	[*]	[*]	[*]	[*]

Taking the third quarter as a representative example, the Inventorship Margin would be calculated as follows:

In Q3 2017, quarterly Net Revenues (excluding AMG827) are [*] and quarterly Net Revenues (AMG827 only) are [*]. The [*]% rate is applied to the [*] in Q3 2017 Net Revenues (excluding AMG827) and the [*]% rate is applied to the [*] in Q3 2017 Net Revenues (AMG827 only). The Inventorship Margin for the quarter is therefore [*] ([*] x [*] + [*] x [*] = [*]).

II. **Collaboration Profit (Loss)**. To determine the Collaboration Profit (Loss) in accordance with Section 7.2.8 (Calculation of Profit (or Loss)), each Party's share of Net Revenues must be determined pursuant to Section 7.2.8.2 (Profits) and Total Costs pursuant to Section 7.2.8.1 (Costs) for the quarter.

Assume for purposes of this example that Net Revenues for Q3 2017 are [*] and the Inventorship Margin is [*] (consistent with the example above). Further assume the following for Q3 2017:

	Total	Amgen	Partner
Net Revenues	[*]	[*]	[*]
Inventorship Margin	[*]	[*]	[*]
Share of Net Revenues	[*]	[*]	[*]
Collaboration Costs	[*]	[*]	[*]
True-Up Payment		[*]	[*]

In such a case, each Party's share of Net Revenues for Q3 2017 would be [*] ([*]-[*] = [*] / [*] = [*]).

Each Party's share of the Total Costs for Q3 2017 would be [*], representing Total Costs of [*] multiplied by the Quarterly Cap of 50% for Q3 2017. In this example, each Party incurred [*] of costs in such quarter, thus no netting would be required.

In this example, Partner would be entitled to a true-up payment from Amgen of [*], representing Partner's share of the Net Revenues less the amount of Net Revenues collected by Partner in Q3 2017 ([*]-[*] = [*]).

If, however, the Total Costs that had been incurred by each Party in the quarter differed, then each Party's share of the Collaboration Profit (Loss) for Q3 2017 for the quarter would need to be adjusted. For this example, assume the following:

	Total	**Amgen**	**Partner**
Net Revenues	[*]	[*]	[*]
Inventorship Margin	[*]	[*]	[*]
Share of Net Revenues	[*]	[*]	[*]
Collaboration Costs	[*]	[*]	[*]
True-Up Payment		[*]	[*]

In such a case, each Party's share of Net Revenues for Q3 2017 would still be [*], ([*]-[*] = [*] / [*] = [*]).

Additionally, each Party's share of the Total Costs for Q3 2017 would still be [*], representing Total Costs of [*] multiplied by the Quarterly Cap of 50% for Q3 2017. However, Partner would owe [*] to Amgen as reimbursement for its share of Total Costs (([*] x [*]) - [*] = [*]).

In this example, Partner would be entitled to a true-up payment of [*], representing Partner's share of the Net Revenues, less (i) the amount of Net Revenues collected by Partner in Q3 2017 and (ii) the amount owed to Amgen to cover Partner's share of Total Costs ([*]-[*] - [*] = [*]).

Schedule
Quality Agreement

Finished Drug Product and Placebo

QUALITY AGREEMENT

Between

AstraZeneca Collaboration Ventures, LLC
Hereafter referred to as “PARTNER”

and

Amgen Inc.
Hereafter referred to as “AMGEN”

This Quality Agreement is intended by the Parties to set forth a plan for the quality assurance groups of AMGEN and PARTNER to work in relation to the manufacture, labeling, packaging, testing, release, shipment and storage of the clinical drug product supply of AMG 139, AMG 157, AMG 181, AMG 557, AMG 827, and the placebo form of the clinical drug products for PARTNER’s use in the Collaboration Territory. The specific details for each molecule will be outlined in addendums to the Quality Agreement. By signing below, the respective quality assurance representatives acknowledge and agree to the provisions of this Quality Agreement.

Agreed and accepted for:		**Agreed and accepted for:**	
Partner		**Amgen Inc.**	
By:	_____	By:	_____
Printed Name:	Michael Kinley	Printed Name:	Astrid McLean
Title:	Sr. Director, Quality Assurance	Title:	Director, Quality Assurance
Date:	_____	Date:	_____

Effective Date: March 30, 2012

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1. BACKGROUND INFORMATION

1.1 Amgen Inc. (hereinafter referred to as “AMGEN”) and Partner (hereinafter referred to as “PARTNER”) (hereinafter referred to individually as “Party” or collectively as “Parties”) have entered into that certain Collaboration Agreement dated as of March 30, 2012 (the “Collaboration Agreement”), pursuant to which AMGEN supplies PARTNER with Drug Product and Placebo.

2. SCOPE

2.1 This Quality Agreement defines the quality obligations of the Parties and their respective affiliates or approved contractors, with respect to the manufacture, labeling, packaging, testing, release, shipment and storage of Product in accordance with the Collaboration Agreement.

2.2 The provisions of this Quality Agreement supplement the provisions of the Collaboration Agreement. The terms of the Collaboration Agreement shall remain in full force and effect. In the event of any conflict between the Collaboration Agreement and this Quality Agreement, the Collaboration Agreement shall govern over the conflict.

2.3 This Quality Agreement may be amended only by mutual written agreement of the Parties.

2.4 Exhibits to this Quality Agreement are intended to provide additional definition to the applicable topic and, as such, should be updated to reflect the current information and business process, as applicable. Amendment of the Exhibits does not require re-approval of the Quality Agreement unless the Quality Agreement itself is affected. Exhibits and all amendments of Exhibits shall be approved by mutually written agreement by the Parties.

2.5 All activities under this Quality Agreement shall be performed in compliance with standard industry practices, regulatory agency guidelines, AMGEN specifications, and all applicable federal, state, and local laws and regulations, including, without limitations, cGMPs.

2.6 This Quality Agreement shall expire at the termination, cancellation, or expiration, as the case may be, of AMGEN’s obligation to supply Drug Product and Placebo for PARTNER’s clinical use.

2.7 PARTNER’s use of Product shall be limited to use in clinical trials approved by the Joint Steering Committee (JSC) as defined in the Collaboration Agreement and where PARTNER has been allocated responsibility to conduct such clinical trials.

3. DEFINITIONS

3.1 All capitalized terms not otherwise defined in this Quality Agreement shall have the definition set forth in the Collaboration Agreement.

3.2 As used in this Quality Agreement, the following terms shall have the following meanings:

CoA	Certificate of Analysis prepared by AMGEN for the Product representing the analytical results of the Product.
CoC	Certificate of Compliance or Quality Assurance Disposition (QAD), prepared by AMGEN for the Product representing that the Product was manufactured according to cGMP requirements.
Disposition Manager	AMGEN Quality Assurance staff member qualified to perform the comprehensive quality assessment and make the disposition decision.
Disposition Package	Documentation set provided to PARTNER representing AMGEN batch disposition of the Product.
Drug Product	AMG 139, AMG 157, AMG 181, AMG 557, AMG 827 Drug Product in finished form as manufactured by AMGEN under the terms of the Collaboration Agreement.
Final Release	Release of Product by AMGEN or PARTNER in accordance with standard operating procedures ("SOPs").
cGMP	All applicable laws and regulations relating to current Good Manufacturing Practices, as promulgated by the United States Food and Drug Administration (FDA) and 'Good Manufacturing Practices as defined in EC Volume IV of The Rules Governing Medical Products in the European Community'.
Manufacturer's Release	Release of Product by AMGEN, according to its SOPs. Manufacturer's Release signifies that Product has been produced using approved processes, in compliance with applicable cGMP regulations, and meets the specifications established for the Product, as determined by review of all appropriate documentation.
Material Change	A change which materially modifies the regulatory filing for the Product or is determined by AMGEN to have significant potential to materially affect the Safety, Quality, Identity, Potency, or Purity of the Product.

Nonconformance	Deviations incurred during the manufacture, labeling, packaging, testing, storage or shipment of the Product, which AMGEN determined to have the potential to impact the Safety, Quality, Identity, Potency, or Purity of the Product, upon preliminary evaluation and required performing an investigation according to AMGEN SOPs.
OOS Result	An examination, measurement or test result that does not conform with pre-established specification requirements established by the relevant Party.
Placebo	A mock treatment or drug that has no effect on the illness, given in a clinical trial to the control group to help differentiate the specific versus non-specific effects of an experimental treatment.
Product	The Drug Product and finished Placebo as manufactured by AMGEN for PARTNER under the terms of the Collaboration Agreement.
Regulatory Agency	A public authority or government agency responsible for protecting and promoting public health through regulation or rulemaking (codifying and enforcing rules and regulations and imposing supervision or oversight for the benefit of the public at large).
Reference Sample	Sample collected from the manufacture of Product for the purpose of being analyzed, should the need arise, to support significant investigations.
Retention Samples	A fully packaged unit from a batch of finished Product stored for identification purposes.
AMGEN Quality Specifications	AMGEN approved set of analytical methods, requirements, and limits as used to judge the identity, purity and potency of all source materials, raw materials, and finished filled, labeled and packaged Product which comprises the Product.
Stock Recovery	The removal or correction of a non-marketed product used in a clinical trial for reasons related to product Safety, Quality, Identity, Potency, or Purity, that has not been marketed or that has not left the direct control of PARTNER.

4. RESPONSIBILITIES

4.1 Without limiting any other provision of this Quality Agreement, the Parties agree that this Quality Agreement is intended to carry out the following guiding principles:

4.1.1 The Parties' quality obligations with respect to the manufacture, labeling, packaging, testing, release, shipment and storage of Product are as set forth in this Quality Agreement and the Collaboration Agreement.

4.1.2 The Parties shall comply with all Applicable Laws in the conduct of activities under this Quality Agreement.

4.1.3 The Parties acknowledge that AMGEN and PARTNER shall each have the right to perform responsibilities hereunder through their Affiliates and contractors.

4.1.4 The Parties shall collaborate to address any disagreements.

5. COMMUNICATION

5.1 AMGEN and PARTNER agree to provide verbal communication to one another, in a timely manner, as necessary or appropriate for a given issue. Both Parties also agree to follow-up and clarify promptly in writing those important verbal communications to ensure clarity of issues. All official communications and documentation between AMGEN and PARTNER will be conducted in English.

5.1.1 The forwarding by PARTNER of any written communication from any global Regulatory Agency concerning the Product outlined in this document shall be done within 3 business days in the original language in which it was received by PARTNER with supplementary comments in English. An English translated version will also be forwarded.

5.1.2 The forwarding of any oral communication from any global Regulatory Agency concerning the Product outlined in this document shall be done within 3 business days in the original language in which the notes concerning the correspondence were taken by PARTNER with supplementary comments in English. An English translated version will also be forwarded.

5.2 Routine verbal and written communications required herein shall be delivered to the individuals indicated in EXHIBIT A or their delegates.

6. BATCH DISPOSITION (PRODUCT RELEASE)

6.1 AMGEN Quality Responsibility

6.1.1 AMGEN shall be responsible for the Manufacturer's Release of the Product to PARTNER.

6.1.2 AMGEN shall provide to PARTNER the Disposition Package for each batch of Product supplied to PARTNER, upon shipment. The documents to be included in the Disposition Package will be outlined in amendments which are specific to the Product.

6.1.3 The Disposition Package for the batch will include a list of Nonconformance(s) incurred during the manufacture, labeling, packaging, testing, or storage of the Product. The list of Nonconformance(s) will include a summary of only lot-specific Nonconformances determined by AMGEN to have significant potential to adversely impact the Safety, Quality, Identity, Potency, or Purity of the Product, according to AMGEN procedures or regulatory filing. Such list will be sent to PARTNER upon shipment of the Product by AMGEN to PARTNER.

6.1.4 AMGEN shall use commercially reasonable efforts to mitigate the risk of Transmissible Spongiform Encephalopathy (TSE) for raw materials and components used during perform of Services per current requirements of Regulatory Agencies and current compendial requirements.

6.2 PARTNER Quality Responsibility

6.2.1 PARTNER shall be responsible for the Final Release of the Product for clinical distribution after reviewing the Disposition Package provided by AMGEN and any shipping records and, if applicable, results of acceptance testing as conducted by a PARTNER qualified laboratory.

6.2.2 In the event PARTNER provides AMGEN with notice of Nonconformance of the Product within 60 days from the date of delivery of Product, AMGEN and PARTNER agree to collaborate to investigate the Nonconformance prior to the disposition of the lot by PARTNER according to each Party's respective failure investigation policies and procedures in accordance with the Quality Agreement.

6.2.3 In the event PARTNER is responsible for a specific European clinical trial, a PARTNER QP or one authorized by PARTNER, will be responsible for certification of Product according to the requirements set out in the European cGMPs.

7. LABEL APPROVAL

7.1 Physical Label Creation and Approval

7.1.1 Physical labels for Product will be generated and approved according to established procedures of AMGEN, for any such activities performed by such Party.

7.1.2 Label Application

7.1.2.1 AMGEN is responsible for labeling and bulk packaging of the clinical supplies.

7.1.2.2 AMGEN shall apply physical labels to Product prior to supply to PARTNER.

8. QUALITY CONTROL

8.1 AMGEN Quality Control Laboratory Testing Responsibility

8.1.1 AMGEN will conduct testing of Product according to AMGEN Quality Specifications and its methods, policies and procedures.

8.2 PARTNER Importation and Testing Responsibility

8.2.1 PARTNER shall be responsible for preparing all documents required for import clearance and entry of shipment with reasonable cooperation from AMGEN. Product batches will be evaluated by PARTNER upon receipt for conformance to applicable import and transport requirements, such as temperature monitoring, damage and documentation requirements.

8.2.2 PARTNER is responsible for sampling upon receipt and conducting testing, as required. Such testing will be conducted by PARTNER (or if AMGEN expressly consent in writing, by appropriately qualified laboratories) by appropriately qualified personnel according to testing procedures mutually agreed by the Parties.

8.2.3 If AMGEN expressly consents to PARTNER using a contract laboratory for import testing, then PARTNER is responsible for shipping Product to its contract laboratory to perform import testing, if necessary.

8.2.4 In the case of OOS, an investigation will be performed per Section 13 (INVESTIGATION OF NONCONFORMANCES, DISCREPANCIES) of this Quality Agreement and PARTNER should notify and obtain consent from AMGEN prior to conducting testing using any other analytical method during the investigation.

8.3 Stability Tesing

8.3.1 AMGEN will conduct routine stability testing of the Product according to AMGEN's clinical stability program requirements.

8.3.2 AMGEN will communicate the expiration of each lot in the Disposition Package.

8.3.3 AMGEN shall notify PARTNER within two (2) business days of any confirmed stability failure of the Product and provide periodic updates on the OOS investigation.

8.3.4 PARTNER will not conduct any stability testing on the Product unless authorized to do so by AMGEN.

8.3.5 AMGEN will provide PARTNER the current Stability Summary Report, including trending, upon request.

9. REFERENCE SAMPLES

9.1 AMGEN shall retain Reference Samples for each manufactured lot of Product released to PARTNER for a minimum of five (5) years after the expiration period. This period may be shortened if the period of stability of the material, as indicated in its specification, is shorter.

10. RETENTION SAMPLES

10.1 PARTNER shall retain Retention Samples for each packaged lot of Product released for clinical distribution per established PARTNER procedure.

11. RECEIVING, SHIPPING, STORAGE and DESTRUCTION

11.1 Unless otherwise agreed by the Parties, AMGEN shall ship Product EXW (Incoterms 2010) AMGEN's facility.

11.2 PARTNER is responsible for reviewing temperature recording data upon receipt of Product shipment.

11.3 PARTNER is responsible for adequate storage of the Product upon receipt according to the storage requirements specified in the product specification.

11.4 Shipping excursions will be investigated per Section 13 (INVESTIGATIONS OF NONCONFORMANCES, DISCREPANCIES) of this Quality Agreement.

11.5 PARTNER is responsible for reviewing temperature recording data of the Product according to the storage requirements if a temperature excursion is identified at a clinical investigation site.

11.5.1 PARTNER notifies AMGEN of any shipping Nonconformances, such as temperature excursions, upon receiving shipping records.

11.5.2 AMGEN shall provide PARTNER adequate training and relevant stability data to support temperature excursions obtained at clinical investigation sites, provided that, AMGEN shall not have any obligation to conduct new tests to support assessment of temperature excursions. If a temperature excursion exceeds any of the limits supported by the stability data, AMGEN shall provide reasonable support to properly assess the product impact, if requested by PARTNER.

11.6 PARTNER shall be responsible for the destruction of any unused and partially used Product in accordance with Applicable Laws and regulations.

12. CHANGE CONTROL

12.1 AMGEN shall notify PARTNER of AMGEN's intention to implement such Material Change and the details of such Material Change for the material changes of manufacturing of the Product, specifically impacting the following documents, if applicable: (1) Analytical Methods, (2) Master Batch/Labeling/Packaging Records, (3) Primary Packaging Components Specifications, (4) Product Specifications, and (5) Raw Material/Component Specifications.

12.2 Within fourteen (14) calendar days after the receipt of such notification, to the extent such Material Change impacts a Regulatory Filing for which PARTNER is the Designated Regulatory Party, PARTNER shall provide to AMGEN a writtenassessment of whether the Material Change constitutes a change which is reportable to Governmental Authorities.

12.3 If a Material Change requires the approval of a Governmental Authority in the Collaboration Territory, then, where PARTNER is the Designated Regulatory Party, PARTNER shall use reasonable efforts to file for such approval within sixty (60) days of receipt of the necessary documentation from AMGEN and obtain necessary regulatory approvals.

12.4 PARTNER shall provide updates to AMGEN of any regulatory submissions relating to said changes.

12.5 PARTNER shall inform AMGEN of any required regulatory change and reporting category in writing within two (2) business days after PARTNER first becomes aware of such information. PARTNER must inform AMGEN of the request in writing, at a minimum the request should describe the proposed change and rationale.

13. INVESTIGATIONS OF NONCONFORMANCES, DISCREPANCIES (POST DISTRIBUTION NC'S)

13.1 If a Nonconformance is identified after a Product batch has been shipped to PARTNER, AMGEN shall inform PARTNER within two (2) business days of such Nonconformance.

13.2 AMGEN will provide support, as necessary and reasonable, to enable PARTNER to comply with applicable regulatory reporting requirements that may result from the occurrence of a post-distribution Nonconformance.

13.3 Each Party shall inform the other Party as soon as reasonably possible of issues which may adversely impact Product quality, safety, efficacy or adverse events relating to the batch of Product received by PARTNER.

14. AUDITS AND INSPECTIONS

14.1 PARTNER Audits

14.1.1 All audits of AMGEN are limited to the facilities where the Products are manufactured, Quality Systems and documentation directly related to the Products, and Batch Records related to lots provided to PARTNER, The scope, agenda, and timeline must be approved by AMGEN prior to each audit.

14.1.2 All audits of AMGEN facilities will be conducted during regular business hours in the presence of AMGEN representatives. Audits shall be conducted by not more than two (2) PARTNER representatives at each AMGEN facility, and, unless otherwise agreed upon by AMGEN, for not more than two (2) business days at each site. PARTNER shall provide AMGEN written notification of such audit no less than one hundred twenty days (120) days in advance. The written notification must clearly state the scope of the audit and regulatory standards to be used to conduct the audit. PARTNER may conduct an audit once in a twelve (12) month period, upon AMGEN's approval of the audit request.

14.1.3 In addition to the annual audit described in Section 14.1.2 above, PARTNER is permitted to request an unplanned "For Cause" audit during the case of a quality or regulatory event. AMGEN will consider any such request in good faith, but will have sole discretion whether or not to grant such request.

14.1.3.1 Such "For Cause" audits require prior written notice by PARTNER to AMGEN and shall be conducted during AMGEN's normal business hours. Each party must approve the audit scope, agenda and timeline prior to conducting the audit. For Cause audits shall be conducted by not more than two (2) PARTNER representatives at each AMGEN facility, and, unless otherwise agreed upon by AMGEN, for not more than two (2) business days.

14.2 Audit Findings

14.2.1 PARTNER shall provide AMGEN a copy of the audit report within thirty (30) calendar days of completion of an audit. After delivery of the audit report, AMGEN shall provide PARTNER with a written response to such report within thirty (30) calendar days from AMGEN's receipt of the report from PARTNER. All information contained in the audit report shall be deemed the confidential information of AMGEN under the Collaboration Agreement.

14.3 Regulatory Agency Inspections

14.3.1 PARTNER shall notify AMGEN immediately upon notification by any Regulatory Agency or other Government Authority of any intended inspection of AMGEN's facilities or records relating to the manufacturing, testing, packaging, labeling, and storage of the Product.

14.3.2 PARTNER shall have the right to have a maximum of one (1) representative present during a regulatory inspection of AMGEN's facilities that perform manufacturing or testing of Product. Presence of PARTNER during an inspection at an AMGEN facility will be according to the direction of AMGEN. PARTNER representative shall not have direct participation during inspection discussions with Regulatory Agency inspector(s).

14.3.3 AMGEN shall provide PARTNER with a copy of the final response immediately after submission to the Regulatory Agency.

14.3.4 PARTNER is responsible for the arrangement of interpreters and translation of documents which may be required by the Regulatory Agency during inspection of AMGEN facilities. AMGEN shall have the right to arrange interpreter and document translation services upon agreement with PARTNER or if PARTNER fails to do so.

15. DISPUTE RESOLUTION

15.1 Disputes relating to non-compliance or nonconformance of Product with the product specifications shall be governed by the terms set forth in the Collaboration Agreement. The provisions of Section 15.3 (choice of law; jurisdiction) of the Collaboration Agreement are deemed incorporated into this Quality Agreement.

16. CUSTOMER COMPLAINTS

16.1 Any information related to customer complaints (i.e., communication that alleges deficiencies relating to the identity, quality, durability, reliability, safety, effectiveness, or performance of a drug, condition of labeling, or packaging, after it is released by PARTNER for clinical studies) shall be forwarded to AMGEN within one (1) business day after PARTNER first becomes aware of such information.

16.2 AMGEN shall investigate according to AMGEN's applicable policy and procedures customer complaints submitted by PARTNER. Complaints which require an AMGEN investigation will be sent to this e-mail address: XXXXXXXXX@amgen.com

16.3 AMGEN shall provide PARTNER with an Interim Report within 30 days and an investigation closure Final Report within forty-five (45) days of receipt of the customer complaint.

17. STOCK RECOVERY

17.1 If any problems are discovered and identified as recall/stock recovery issues related to the Product, the discovering Party shall notify the other immediately.

17.2 PARTNER and AMGEN shall each notify the other Party within three (3) business days if it becomes aware that any Product is alleged or proven to be the subject of a recall or stock recovery in the Collaboration Territory.

17.3 The Parties shall meet to discuss the circumstances that merit the Product recall or stock recovery and to determine the appropriate course of action. Such course of action shall be consistent with the internal SOP of the Party having the right to control such recall pursuant to this section.

17.4 If either Party proposes to initiate a Stock Recovery or other corrective action with respect to the Product in the Collaboration Territory, the Parties will promptly discuss such proposed action. Any decisions by the Parties shall be governed by the terms of the Collaboration Agreement. The Parties shall cooperate, as reasonably necessary, in the implementation of such actions.

17.5 The Parties shall cooperate and promptly perform investigations into the root causes leading up to the Product Stock Recovery, when appropriate. Investigation reports regarding the defect or cause for such regulatory reporting shall be provided to the corresponding Party within an appropriate timeframe dependent on regulatory reporting requirements.

17.6 The Parties shall each maintain complete and accurate records of any Stock Recovery it has the right to control pursuant to this section of the Quality Agreement for such periods as may be required by legal requirements, but in any event for no less than three (3) years from the date of Stock Recovery.

17.7 Each Party maintains the responsibility for Product distributed within the Collaboration Territory for its own clinical studies.

18. RESPONSIBLE PERSONS: CONTACT INFORMATION

18.1 The individuals listed in EXHIBIT A shall be the key points of contact between AMGEN and PARTNER relating to the rights and obligations of the Parties in this Quality Agreement. The responsible individuals, or their respective delegates, must be notified in official communications as required by this Quality Agreement.

EXHIBIT A

Responsible Persons and Contact Information

AMGEN			
Name	**Email Address**	**Contact Number**	**Responsibility**
xxxxxxxxx	xxxxxxxxx	xxxxxxxxx	Manager, International Quality
xxxxxxxxx	xxxxxxxxx	xxxxxxxxx	Director, International Quality

PARTNER			
Name	**Email Address**	**Contact Number**	**Responsibility**
xxxxxxxxx	xxxxxxxxx	xxxxxxxxx	Director of QA and EU QP
xxxxxxxxx	xxxxxxxxx	xxxxxxxxx	Senior Director, Quality Assurance

Exhibit A Version Date: March 30, 2012

Agreed and accepted for:

Partner

By: _____

Printed Name: Michael Kinley

Title: Sr. Director, Quality Assurance

Date: _____

Agreed and accepted for:

Amgen Inc.

By: _____

Printed Name: Astrid McLean

Title: Director, Quality Assurance

Date: _____

Schedule
Stage 1 Clinical Trial

Product	Stage 1 Clinical Trial
AMG139	[*]
AMG157	[*]
AMG181	[*]
AMG557	[*]
AMG827	[*]

EXHIBIT 10.47

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 THE
COLLABORATION AGREEMENT

This Amendment No. 1 to the Collaboration Agreement (this "**Amendment**") is entered into as of the 1st day of October, 2014 (the "**Amendment Effective Date**") by and between **Amgen Inc.**, a Delaware corporation with a place of business at One Amgen Center Drive, Thousand Oaks, California 91320 ("**Amgen**"), and **AstraZeneca Collaboration Ventures, LLC**, a Delaware limited liability company with a place of business at 1800 Concord Pike, Wilmington, Delaware 19850 ("**Partner**"). Amgen and Partner are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**". AstraZeneca Pharmaceuticals LP, the parent corporation of Partner ("**AstraZeneca**"), [*] of the Agreement (as defined below) is a party to this Amendment [*].

WHEREAS, Amgen and Partner entered into that certain Collaboration Agreement, dated as of March 30, 2012 (the "**Agreement**");

WHEREAS, Amgen and Partner wish to update certain portions of the Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants hereinafter set forth, the Parties hereto agree to amend the Agreement as follows:

ARTICLE 1 - AMENDMENT

Capitalized terms used in this Amendment and not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

1.1 **Amendment to Certain Definitions.** The Parties hereby agree that the following defintions in the Agreement are hereby deleted in their entirety and replaced with the following:

"Excluded Territory" means (i) with respect to AMG557 and AMG570, Japan, and (ii) with respect to AMG827, all countries not included within the AMG827 Territory.

"Excluded Territory Agreement" means (i) in relation to AMG827, the AMG827 Technology Transfer Agreement by and among Kyowa Hakko Kirin Co., Ltd., Amgen and Kirin-Amgen, Inc., the Research, Development and Technology Disclosure Agreement: AMG827 by and among Kyowa Hakko Kirin Co., Ltd., Amgen and Kirin-Amgen, Inc., and the AMG827 License Agreement between Kirin-Amgen, Inc., all dated October 29, 2010 and (ii) in relation to AMG557 and AMG570, means the License Agreement by and between Amgen and Takeda Pharmaceutical Company Limited dated February 1, 2008, in each case as the same have been amended and may be amended from time to time hereafter in accordance with terms of this Agreement.

Amendment to Certain Schedules. The Parties hereby agree that the following schedules to the Agreement are hereby deleted in their entirety and replaced with the schedules set forth in Appendix I attached hereto:

Development/Commercial Lead Schedule;

Distracting Product Schedule;

Products Schedule; and

Stage 1 Clinical Trial Schedule.

1.2 **Acknowledgement.** The Parties hereby acknowledge that (a) in accordance with Section 9.4 (Pre-Clinical Research and Development Programs) of the Agreement, the Inventorship Margin for AMG570 shall be [*] percent ([*]%), and (b) in accordance with Section 9.3.3 (Inclusion) of the Agreement, (i) all Development Costs and General Costs for AMG570 shall be shared on a [*] basis, and (ii) all Net Revenues for AMG570 shall, after the deduction of the Inventorship Margin for AMG570, be shared on a [*] basis.

1.3 **Manufacturing Lead.** The Parties hereby agree that, notwithstanding the provisions of Section 4.1 (Allocation of Manufacturing Responsibility) of the Agreement to the contrary, Amgen shall not be required to elect whether or not to continue as the Manufacturing Lead for AMG570 and AMG557 until [*].

ARTICLE 2 – REFERENCE TO AND EFFECT ON THE AGREEMENT

2.1 **Reference to Agreement.** Upon and after the effectiveness of this Amendment, each reference in the Agreement to "this Agreement", "hereunder", "hereof" or words of like import referring to the Agreement shall mean and be a reference to the Agreement as modified and amended hereby.

2.2 **Effectiveness of Amendment.** Upon execution and delivery of this Amendment by both Parties, the amendments set forth above shall be effective as of the Amendment Effective Date. Except as specifically amended above, the Agreement is and shall continue to be in full force and effect and is hereby in all respects ratified and confirmed and shall constitute the legal, valid, binding and enforceable obligations of the Parties.

2.3 **No Waiver.** The execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of either Party under the Agreement, nor constitute a waiver of any provision of the Agreement.

ARTICLE 3 – MISCELLANEOUS

3.1 **Governing Law.** This Amendment will be governed by, and enforced and construed in accordance with, the laws of the State of New York without regard to its conflicts of law provisions. Each of the Parties hereby irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the state and federal courts of the State of New York for any matter arising out of or relating to this Amendment and the transactions contemplated hereby, and agrees not to commence any litigation relating thereto except in such courts. Each of the Parties hereby irrevocably and unconditionally waives any objection to the laying of venue of any matter arising out of this Amendment or the transactions contemplated hereby in the state and federal courts of the State of New York and hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such matter brought in any such court has been brought in an inconvenient forum. The Parties agree that a final judgment in any such matter will be conclusive and may be enforced in other jurisdictions by suits on the judgment or in

any other manner provided by law. Any proceeding brought by either Party under this Amendment will be exclusively conducted in the English language. The United Nations Convention for the International Sale of Goods will not apply to the transactions contemplated herein.

3.2 **Headings.** The heading for each article and section in this Amendment has been inserted for convenience of reference only and is not intended to limit or expand on the meaning of the language contained in the particular article or section.

3.3 **Counterparts.** This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Signature page follows]

IN WITNESS THEREOF, duly authorized representatives of the Parties hereto have executed this Amendment as of the date first set forth above.

ASTRAZENECA COLLABORATION VENTURES, LLC

By:	/s/ Pascal Soriot
Name:	Pascal Soriot
Title:	CEO

AMGEN INC.

By:	/s/ Robert A. Bradway
Name:	Robert A. Bradway
Title:	Chairman and Chief Executive Officer

ASTRAZENECA PHARMACEUTICALS LP

By:	/s/ Pascal Soriot
Name:	Pascal Soriot
Title:	CEO

Appendix I
Schedules

Schedule
Development/Commercial Lead

Amgen	Partner
AMG827	AMG139
AMG557	AMG157
AMG570	AMG181

AMG827 Respiratory-

1 Specifically with regard to AMG827 at the global level, the Parties will work closely through the JPT on the commercial strategy for the Respiratory market for AMG827 with Amgen taking the primary responsibility for [*].

2 The Parties will [*].

3 The Parties will cooperate to ensure that [*] is made available to the JPT at both the global and regional level.

4 This arrangement will be noted in the press release and other approved communications as "[*]," or with words of similar import.

AMG570-

The Parties hereby agree that Amgen shall be the initial Development Lead and Commercial Lead for AMG570. The Parties shall [*], provided that, in the event that the Parties are unable to [*] if it elects to do so.

Schedule
Distracting Product

Product	Product Target	Distracting Target*
AMG 139	[*]	[*]
AMG 157	[*]	[*]
AMG 181	[*]	[*]
AMG 557	[*]	[*]
AMG 570	[*]	[*]
AMG 827	[*]	[*]

*Distracting Target includes (i) any **[*]**; (ii) any **[*]**; (iii) any **[*]**; (iv) any **[*]**; and (v) any **[*].** For avoidance of doubt, the Distracting Product Schedule lists without limitation **[*]**.

Notwithstanding anything contained in the Agreement to the contrary, Amgen's **[*] program referred to internally at Amgen as **[*]** shall not be a Distracting Product so long as such molecule is the subject of that certain License Agreement dated as of **[*]** by and between Amgen and **[*]**, as amended.

Schedule
Products

Product
AMG 139
AMG 157
AMG 181
AMG 557
AMG 827
AMG 570

Schedule
Stage 1 Clinical Trial

Product	Stage 1 Clinical Trial
AMG139	[*]
AMG157	[*]
AMG181	[*]
AMG557	[*]
AMG827	[*]
AMG570	[*]

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.

August 4, 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.

August 4, 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 June 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.

August 4, 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 June 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.

August 4, 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.